EV807884909US

CUSTOMER NUMBER: 000031425

Date: 15 May 2006
Inventor: Burrows et al.
Title: DENTAL ANESTHESIA ADMINISTRATION MASK/EYE SHIELD
Application. No.: 10/647,991
Filing Date: 26 August 2003
Attorney Docket: 7432-0046

X Transmittal Sheet (in duplicate)
X Amendment Under Section 1.111
X Exhibits A and B
X One (1) month Extension of Time
X Check for $370.00
X Return post card

THE STAMP OF THE PATENT OFFICE HEREON INDICATES RECEIPT OF THE ABOVE-LISTED PAPERS.

46 - Postcard for Amendment Response to Official Action 15 May 2006.wpd

INDIANO VAUGHAN LLP

One North Pennsylvania Street, Suite 850
Indianapolis, Indiana 46204
Phone 317-822-0033; Fax 317-822-0055

PATENT APPLICATION

Art Unit: 3743
Examiner: Ali, Shumaya B
Atty. Docket: 7432-0046
Applicants: Moenning and Iribeck
Invention: DENTAL ANESTHESIA ADMINISTRATION MASK AND EYE SHIELD
Serial No.: 10/647,991
Filed: 26 August 2003

CUSTOMER NUMBER: 000031425

Box Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

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I hereby certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service as "Express Mail, Post Office to Addressee" by the certificate number set forth below, in an envelope addressed to:

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Dated: 15 May 2006

Signature: Marianne E. Ries

Marianne E. Ries

Exp. Cert. No.: EV 807884909 US

Deposit Account:
The Commissioner is hereby authorized to deduct any defect or deficiency in fee, or credit any overpayment to:
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Dear Sir:

Transmitted herewith is a response in the above-identified application:

The fee has been calculated as shown below:

CLAIMS AS AMENDED							
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NO. PREVIOUSLY PAID FOR	NUMBER EXTRA	SMALL ENTITY		OTHER	
TOTAL CLAIMS	35	34*	1	Rate x $25	$ 0.00	Rate x $50	$50 .00
INDEP. CLAIMS	6	5**	0	Rate x $100	$0.00	Rate x $200	$ 200.00
TOTAL FEE FOR ADDITIONAL CLAIMS							**$250.00**

* If the "Highest Number Previously Paid For" in this space is less than 20, write "20" in this space.
** If the "Highest Number Previously Paid For" in this space is less than 3, write "3" in this space.

X An Extension of Time for 1 month (or however many months is necessary) is hereby requested under 37 C.F.R. 1.136(a).
The required fee for filing this extension is: **$ 120.00**

TOTAL FEE FOR THIS AMENDMENT **$ 370.00**

X A check in the amount of **$370.00** to cover the total fee for this amendment is attached.

_____ Applicant asserts that it is entitled to Status as Small Entity Under 37 C.F.R. 1.27.

The Commissioner is hereby authorized to charge any additional filing fees under 37 C.F.R. 1.16 or processing fees under 37 C.F.R. 1.17 which may be required during the prosecution of this application, or credit of any overpayment, to **E. Victor Indiano's Deposit Account No. 50-1590.** A duplicate copy of this sheet is enclosed.

Attorney of Record
Printed Name: **E. Victor Indiano**
Registration No.: **30,143**

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Printed Name: **E. Victor Indiano**
Registration No.: **30,143**

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit: **3743**

Examiner: **Ali, Shumaya B**

Atty. Docket: **7432-0046**

Applicants: **Moenning and Irlbeck**

Invention: **DENTAL ANESTHESIA ADMINISTRATION MASK AND EYE SHIELD**

Serial No.: **10/647,991**

Filed: **26 August 2003**

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P.O. Box 1450
Alexandria VA 22313-1450

CUSTOMER NUMBER: 000031425

AMENDMENT UNDER 37 C.F.R. § 1.111

Dear Sir:

In response to the official Action of 25 January 2006, Applicants respectfully request entry of the following amendment.

IN THE DRAWINGS

Please amend Fig 4B, as indicated in red in the attached sheets of drawings labeled as "Marked up Versions". The changes indicated in the marked up versions have been incorporated into the claim drawing sheet showing Fig 4B and properly labeled as a "REPLACEMENT SHEET"

New Formal drawings incorporating the changes made therein will be submitted upon receiving an indication from the examiner that the changes to the drawings are acceptable.

IN THE SPECIFICATION

Please amend page 24, lines 17-22; and page 25, lines 1-5 as follows:

The first and second nasal cannulas 180, 184 are generally flexible pieces of respiratory tubing used with anesthesia devices. The first nasal cannula 180 has a source end 179, ~~and~~ a patient end 181, and a middle portion 193 disposed between the source end 179 and the patient end 181. The second nasal cannula 184 has a source end 183, ~~and~~ a patient end 185, and a middle portion 195 disposed between the source end 183 and the patient end 185. The source end 179 of the first nasal cannula 180 is connected to the patient end 171 of the first patient connector 172 of the mask connector 170. The source end 183 of the second nasal cannula 184 is connected to the patient end 173 of the second patient connector 174 of the mask connector 170. The inspiratory gas coming from the first patient connector 172 of the mask connector 170 enters the source end 179 of the first nasal cannula 180 and exits through the patient end 181. The inspiratory gas coming from the second patient connector 174 of the mask connector 170 enters the source end 183 of the second nasal cannula 184 and exits through the patient end 185.

IN THE CLAIMS

Please amend Claim 1, 21, 25, 30, and 36-39 as follows:

Please cancel Claims 9 and 12

Please add new Claims 40 and 41:

1.(Currently Amended) An anesthesia delivery device ~~for use on a patient having a mouth and a nose having a naris, the delivery device being~~ capable of being coupled to a ventilation system having an inspiratory gas input for delivering gas to ~~the~~ a patient and an exhaust gas output for delivering gas from a the patient to the ventilation system, the anesthesia delivery device comprising:

an inspiratory gas line having a machine end and a patient end portion, the machine end being capable of being fluidly coupled to the inspiratory gas input of the ventilation system, and the patient end portion being configured for being received within the naris of the patient for delivering inspiratory gas to the naris of the patient,

a face mask comprising a dome portion sized to cover the patient's nose without covering the patient's mouth, the dome portion defining an inside air space between the patient's nose and the dome portion, and an outside air space exterior of the dome portion, the dome portion including a gas port, the patient end portion comprising a flexible cannula having a source end disposed in the outside air space, a middle portion extending through the dome portion, and a patient end configured for being received within the naris of the patient for delivering inspiratory gas to the naris of the patient, the gas port of the face mask being sized to slidably receive the flexible cannula for permitting the user to move

the cannula relative to the face mask and gas port to enable a user to place an end of the flexible cannula in a desired position within the naris of the patient

a vent for allowing gas to pass between the inside air space and the outside air space, and

an exhaust port capable of being fluidly coupled to the exhaust gas output of the ventilation system for allowing gas to pass from the inside air space to the exhaust gas output of the ventilation system;

wherein the exhaust port and vent are capable of cooperatively exerting a negative pressure on the outside air space adjacent to the face mask for preventing inspiratory gases from entering the outside air space adjacent to the face mask.

2. (Original) The anesthesia delivery device of Claim 1 further comprising an eye shield having a shield attachment mechanism for attaching the eye shield to the face mask such that the eye shield covers the eyes of the patient.

3. (Cancelled)

4. (Cancelled)

5. (Previously Presented) The anesthesia delivery device of Claim 1 wherein the vent is formed as a part of the face mask.

6. (Previously Presented) The anesthesia delivery device of Claim 5 further comprising a cushion member attached to the lower edge of the dome portion of the face mask, wherein the cushion member contains a bladder filled with a gas, and is scented.

7. (Cancelled)

8. (Cancelled)

9. (Cancelled)

10. (Original) The anesthesia delivery device of Claim 1 wherein the inspiratory gas line comprises a mask connector member for connecting the inspiratory gas line to the face mask.

11. (Original) The anesthesia delivery device of Claim 10 wherein the inspiratory gas line further comprises a first side line, a second side line, and a slide member; wherein inspiratory gases pass between the machine end and the patient end of the inspiratory gas line through both the first side line and the second side line; wherein the slide member surrounds the first and second side lines and is slideable along the first and second side lines allowing the first and second side lines to be placed on opposite sides of the patient's head and the slide member can be positioned to create a snug fit of the inspiratory gas line around the head of the patient to hold the anesthesia delivery device in place.

12. (Cancelled)

13. (Withdrawn- Previously Presented) The anesthesia delivery device of Claim 1 further comprising an exhaust connector connected to the exhaust port of the face mask and capable of being fluidly coupled to the exhaust gas output of the ventilation system for allowing gas to pass from the inside air space to the exhaust gas output of the ventilation system, the exhaust connector including the vent, wherein the vent comprises a one way valve for permitting air to flow into the exhaust connector from the outside air space, while preventing air from flowing to the outside air space from the exhaust connector.

14. (Withdrawn- Previously Presented) The anesthesia delivery device of Claim 13 further comprising a strap for attaching the anesthesia delivery device to the patient's head, wherein the face mask further comprises a left post extending into the outside air space on one side of the exhaust port and a right post extending into the outside air space on the opposite side of the exhaust port; and wherein the strap further comprise a first attachment point and a second attachment point; the first attachment point being capable of attachment to the right post of the face mask and the second attachment point being capable of attachment to the left post of the face mask.

15. (Withdrawn - Previously Presented) The anesthesia delivery device of Claim 13 further comprising an exhaust line attached to the exhaust port of the face mask, and a strap for attaching the anesthesia delivery device to the patient's head, wherein the strap further

comprises an attachment mechanism for attaching to the exhaust line to secure the anesthesia delivery device to the patient's head.

16. (Withdrawn- Original) The anesthesia delivery device of Claim 15 wherein the attachment mechanism of the strap is a slit in the strap, wherein the slit is capable of being placed around the exhaust line.

17. (Withdrawn- Previously Presented) The anesthesia delivery device of Claim 13 further comprising a strap for attaching the anesthesia delivery device to the patient's head, wherein the strap further comprises a right side having a proximal end and a distal end, the proximal end of the right side of the strap being attached to the face mask on the right side of the patient's head and the distal end of the right side having a first fastening piece; and a left side having a proximal end and a distal end, the left side of the patient's head and the distal end of the left side having a second fastening piece; the first fastening piece being capable of being mainly connected to the second fastening piece.

18. (Withdrawn- Original) The anesthesia delivery device of Claim 17 wherein the first fastening piece comprises the hook material of a Velcro fastener, and the second fastening piece comprises the eye material of a Velcro fastener.

19. (Previously Presented) The anesthesia delivery device of Claim 1 wherein the vent comprises an aperture in the face mask.

20. (Withdrawn- Original) The anesthesia delivery device of Claim 1 wherein the vent is a one-way flow valve allowing the flow of gas into the inside air space of the dome portion of the mask through the vent, but not allowing the flow of gas out of the inside air space of the dome portion of the mask through the vent.

21. (Currently Amended) An anesthesia delivery device ~~for use on a patient having a mouth and a nose having a naris, the delivery device being~~ capable of being coupled to a ventilation system having an inspiratory gas input for delivering gas to ~~the~~ a patient and an exhaust gas output for delivering gas from a the patient to the ventilation system, the anesthesia delivery device comprising:

an inspiratory gas line having a machine end and a patient end portion, the machine end being capable of being fluidly coupled to the inspiratory gas input of the ventilation system, and the patient end portion being configured for being received within ~~the~~ a naris of the patient for delivering inspiratory gas to the naris of the patient,

a facemask comprising a dome portion sized to cover the patient's nose without covering the patient's mouth, and an inspiratory gas port the dome portion defining an inside air space between the patient's nose and the dome portion, and an outside air space exterior of the dome portion, and an exhaust port; ,

the patient end portion comprising a flexible cannula having a source end disposed in the outside air space, a middle portion extending through the dome portion, and a patient end configured for being received within the naris of the

patient for delivering inspiratory gas to the naris of the patient, the inspiratory gas port of the face mask being sized to slidably receive the flexible cannula for permitting the user to slidably move the cannula relative to the face mask and inspiratory gas port to place the patient end of the flexible cannula in a desired position within the naris of the patient,

a vent for allowing gas to pass between the inside air space and the outside air space, and

an exhaust connector connected to the exhaust port of the face mask and capable of being fluidly coupled to the exhaust gas output of the ventilation system for allowing gas to pass from the inside air space to the exhaust gas output of the ventilation system;

wherein the exhaust port and vent are capable of cooperatively exerting a negative pressure on the outside air space adjacent to the face mask for preventing inspiratory gases from entering the outside air space adjacent to the face mask.

22. (Withdrawn- Previously Presented) The anesthesia delivery device of Claim 21 wherein the exhaust connector is bifurcated, having a first leg, a second leg and a third leg wherein gas can flow freely between the first, second and third legs; the first leg being attached to the exhaust port, the second leg capable of being fluidly coupled to the exhaust gas output of the ventilation system, the third leg coupled to the vent, the vent comprising a one-way flow valve allowing the flow of gas into the exhaust connector through the third leg but not allowing the flow of gas out of the third leg through the vent.

23. (Withdrawn- Original) The anesthesia delivery device of Claim 22 wherein the exhaust connector is T-shaped.

24. (Currently Amended) An anesthesia delivery device ~~for use on a patient having a forehead, a mouth and a nose having a naris, the delivery device being~~ capable of being coupled to a ventilation system having an inspiratory gas input for delivering gas to ~~the~~ a patient and an exhaust gas output for delivering gas from ~~a~~ the patient to the ventilation system, the anesthesia device comprising:

a face mask comprising a dome portion having a lower edge, the dome portion being sized to cover the patient's nose without covering the patient's mouth, the dome portion defining an inside air space between the patient's nose and the dome portion, and an outside air space exterior of the dome portion, a cushion member attached to the lower edge of the dome portion, and an exhaust port for allowing gas to pass from the inside air space of the dome portion;

a vent for allowing gas to pass between the inside air space and the outside air space,

an exhaust port for allowing gas to pass from the inside air space of the dome portion, the exhaust port including an elbow;

an inspiratory port;

an inspiratory gas line having a machine end and a patient end, the machine end being located in the outside air space and being capable of being fluidly coupled to the inspiratory gas input of the ventilation system, and the

patient end being located in the inside air space and being configured for being received within the naris of the patient for delivering inspiratory gas to the naris of the patient, the inspiratory gas line passing from the outside air space into the inside air space through the inspiratory port; and

an exhaust line having a machine end and a patient end, the machine end being capable of being fluidly coupled to the exhaust gas output of the ventilation system, and the patient end being connected to the elbow of the exhaust port for scavenging gases from the inside air space of the dome portion, the exhaust line being positioned by the elbow to extend over the forehead of the patient;

wherein the exhaust port and vent are capable of cooperatively exerting a negative pressure on the outside air space adjacent to the face mask for preventing inspiratory gases from entering the outside air space adjacent to the face mask.

25. (Currently Amended) The anesthesia delivery device of Claim 24 wherein the inspiratory port of the face mask is sized to slidably but snugly receive the flexible cannula for permitting the user to move the cannula relative to the face mask and inspiratory gas port to enable a user to adjust the length of the cannula within the inside air space so that the cannula is properly positioned within the naris of the patient the cushion member is a bladder filled with a gas; and wherein the face mask further comprises an inflation valve for increasing or decreasing the gas pressure within the bladder; and wherein the eye shield further comprises an aperture sized and located to fit around the inflation valve.

26. (Original) The anesthesia delivery device of Claim 24 wherein the inspiratory gas line further comprises a first side line, a second side line, and a slide member; wherein inspiratory gases pass between the machine end and the patient end of the inspiratory gas line through both the first side line and the second side line; wherein the slide member surrounds the first and second side lines and is slideable along the first and second side lines allowing the first and second side lines to be placed on opposite sides of the patient's head and the slide member can be positioned to create a snug fit of the inspiratory gas line around the head of the patient to hold the anesthesia delivery device in place.

27. (Original) The anesthesia delivery device of Claim 24 further comprising a strap for attaching the anesthesia delivery device to the patient's head.

28. (Withdrawn- Original) The anesthesia delivery device of Claim 27 wherein the strap has a right end, a left end and a central portion being disposed between the right end and the left end; and further comprises an aperture located in the central portion, the aperture being fit around the exhaust line for attaching the strap to the anesthesia delivery device, a first fastening piece located on the right end of the strap, and a second fastening piece located on the left end of the strap, the first fastening piece being capable of being mainly connected to the second fastening piece for attaching the anesthesia delivery device to the patient's head.

29. (Withdrawn- Original) The anesthesia delivery device of Claim 24 wherein the vent is a one-way flow valve allowing the flow of gas into the inside air space of the dome portion of the

mask through the vent, but not allowing the flow of gas out of the inside air space of the dome portion of the mask through the vent.

30. (Currently Amended) An anesthesia delivery device ~~for use on a patient having a mouth and a nose having a naris, the delivery device being~~ capable of being coupled to a ventilation system having an inspiratory gas input for delivering gas to ~~the~~ a patient and an exhaust gas output for delivering gas from ~~a~~ the patient to the ventilation system, the anesthesia delivery device comprising:

a face mask comprising

a dome portion having a lower edge, the dome portion being sized to cover the patient's nose without covering the patient's mouth, the dome portion defining an inside air space between the patient's nose and the dome portion, and an outside air space exterior of the dome portion,

a flow vent for allowing the flow of gas into the inside air space through the vent, ~~but not allowing the flow of gas out of the inside air space through the vent~~,

an exhaust port for allowing gas to pass from the inside air space of the dome portion; and

an inspiratory port;

an inspiratory gas line having a machine end and a patient end portion, the machine end being located in the outside air space and being capable of being fluidly coupled to the inspiratory gas input of the ventilation system, and the

patient end portion ~~being located in the inside air space and being configured for being received within the naris of the patient for delivering inspiratory gas to the naris of the patient~~, the patient end portion comprising a flexible cannula having a source end disposed in the outside air space, a middle portion slidably but snugly received in the inspiratory port to extend through the dome portion, and a patient end configured for being received within the naris of the patient for delivering inspiratory gas to the naris of the patient,

an exhaust line having a machine end and a patient end, the machine end being capable of being fluidly coupled to the exhaust gas output of the ventilation system, and the patient end being connected to the exhaust port for scavenging gases from the inside air space of the dome portion; and

an eye shield having a shield attachment mechanism for attaching the eye shield to the face mask such that the eye shield covers the eyes of the patient;

wherein the exhaust port and vent are capable of cooperatively exerting a negative pressure on the outside air space adjacent to the face mask for preventing inspiratory gases from entering the outside air space adjacent to the face mask.

31. (Cancelled)

32. (Withdrawn -Previously Presented) The anesthesia delivery device of Claim 30 wherein the face mask includes a scenting material to impart a scent to the face mask.

33. (Withdrawn - Original) The anesthesia delivery device of Claim 32 wherein the scenting material is chosen from a group of scenting materials including fruit scented scenting materials, candy scented scenting materials, flower scented scenting materials, spice scented scenting materials, potpourri scented scenting materials, perfume scented scenting material, gum scented scenting materials, food scented scenting material, and plant scented scenting materials.

Please add the following new Claims 34 - 39 as follows:

34. (Previously Presented) The anesthesia delivery device of Claim 1 wherein the patient end portion includes a second flexible cannula having a source end disposed in the outside air space, a middle portion extending through the dome portion, and a patient end configured for being received within the naris of the patient for delivering inspiratory gas to the naris of the patient,

35. (Previously Presented) The anesthesia delivery device of Claim 34 wherein each of the first and second cannulas comprise flexible respiratory tubing.

36. (Currently Amended) The anesthesia delivery device of Claim 1 wherein ~~the dome portion includes a first inspiratory port through which the middle portion of the first cannula passes,~~ the first inspiratory port is ~~being~~ sized for slidably but snugly receiving the first cannula therein to permit the user to vary the length of the first cannula within the inside air space and for snugly engaging the first cannula to resist movement of the first cannula when not being moved by the user.

37. (Currently Amended) The anesthesia delivery device of Claim 36 wherein the patient end portion includes a second flexible cannula having a source end, ~~disposed in the outside air space,~~ a middle portion, ~~extending through the dome portion,~~ and a patient end, ~~configured for being received within the naris of the patient for delivering inspiratory gas to the naris of the patient;~~ ~~and~~

wherein the dome portion includes a second inspiratory port through which the middle portion of the second cannula passes, the second inspiratory port being sized for slidably but snugly receiving the second cannula therein to permit the user to vary the length of the second cannula within the inside air space and for snugly engaging the second cannula to resist movement of the second cannula when not being moved by the user.

38. (Currently Amended) An anesthesia delivery device ~~for use on a patient having a mouth, a forehead and a nose having a naris, the delivery device being~~ capable of being coupled to a ventilation system having an inspiratory gas input for delivering gas to ~~the~~ a patient and an exhaust gas output for delivering gas from a the patient to the ventilation system, the anesthesia delivery device comprising:

an inspiratory gas line having a machine end and a patient end portion, the machine end being capable of being fluidly coupled to the inspiratory gas input of the ventilation system, and the patient end portion being configured for being received within the naris of the patient for delivering inspiratory gas to the naris of the patient,

a face mask comprising a dome portion sized to cover the patient's nose without

covering the patient's mouth, the dome portion defining an inside air space between the patient's nose and the dome portion, and an outside air space exterior of the dome portion,

a vent for allowing gas to pass between the inside air space and the outside air space,

an exhaust port capable of being fluidly coupled to the exhaust gas output of the ventilation system for allowing gas to pass from the inside air space to the exhaust gas output of the ventilation system, the exhaust port including an elbow, and

an exhaust line having a machine end and a patient end, the patient end being connected to the elbow of the exhaust port for scavenging gases from the inside air space of the dome portion, the exhaust line being positioned by the elbow to extend over the forehead of the patient

wherein the exhaust port and vent are capable of cooperatively exerting a negative pressure on the outside air space adjacent to the face mask for preventing inspiratory gases from entering the outside air space adjacent to the face mask.

39. (Currently Amended) The anesthesia delivery device of Claim 38 wherein the patient end portion comprising a flexible cannula having a source end disposed in the outside air space, a middle portion slidably but snugly received by, and extending through ~~the dome portion,~~ an inspiratory port in the face mask, and a patient end configured for being received within the naris of the patient for delivering inspiratory gas to the naris of the patient.

Please add new claims 40 and 41

40. (New) The anesthesia delivery device of Claim 1 wherein the inspiratory gas port of the face mask is sized to slidably but snugly receive the flexible cannula relative to the face mask and gas port to enable a user to adjust the length of the cannula within the inside air space so that the cannula is properly positioned within the naris of the patient.

41. (New) An anesthesia delivery device capable of being coupled to a ventilation system having an inspiratory gas input for delivering gas to a patient and an exhaust gas output for delivering gas from a the patient to the ventilation system, the anesthesia delivery device comprising:

an inspiratory gas line having a machine end and a patient end portion, the machine end being capable of being fluidly coupled to the inspiratory gas input of the ventilation system, and the patient end portion being configured for being received within the naris of the patient for delivering inspiratory gas to the naris of the patient,

a face mask comprising a dome portion sized to cover the patient's nose without covering the patient's mouth, the dome portion defining an inside air space between the patient's nose and the dome portion, and an outside air space exterior of the dome portion,

the patient end portion comprising a flexible cannula having

a source end disposed in the outside air space,

a middle portion extending through the dome portion, and having a length disposed within the dome portion, wherein the length of the middle portion disposed within the dome portion is variable by the user, and

a patient end disposed within the dome portion and being configured for being received within the naris of the patient for delivering inspiratory gas to the naris of the patient,

a vent for allowing gas to pass between the inside air space and the outside air space, and

an exhaust port capable of being fluidly coupled to the exhaust gas output of the ventilation system for allowing gas to pass from the inside air space to the exhaust gas output of the ventilation system;

wherein the exhaust port and vent are capable of cooperatively exerting a negative pressure on the outside air space adjacent to the face mask for preventing inspiratory gases from entering the outside air space adjacent to the face mask.

REMARKS

I. OVERVIEW

In the Official Action, the Examiner raised a host of technical objections to the claims based on 35 U.S.C. Sections 101 and 112. Additionally, the Examiner rejected some of the claims on substantive grounds based on 35 U.S.C. Section 103. To support these substantive rejections, the Examiner cited previously cited art, along with two newly found references including McAuley U.S. Patent Application Publication 2003/0094178, and Barrett, U.S. Patent No. 6,412,488.

With this Response, the Applicants have amended the Specification, the Claims and the Drawings, were necessary, to overcome the Examiner's technical objections. Additionally, the Applicants have amended the claims where necessary, to point out those features that patentably distinguish the Applicants' invention from the art of record.

As set forth in more detail below, the changes made to various parts of the Specification are believed to overcome the technical objections. It is believed that the claims of the application are now in condition for allowance, as none of the art of record discloses or suggests the Applicants' claimed invention.

II. REJECTION UNDER SECTION 101

The Examiner first rejected the claims under Section 101. In particular, the Examiner believed that several of the claims were directed to non-statutory matter such as "a patient having a forehead, a mouth and a nose having a naris".

In this regard, the Applicants would like the Examiner to first note that no where in the claims, were the Applicants attempting to claim the non-statutory subject matter of a human being, or the body parts of a human being, such as a forehead, mouth and a nose having a naris. Rather, these body parts were inserted into the claim, to help clarify features relating to the apparatus of the claim, such as the positioning of the mask, that covers the nose but not the mouth; the naris of the nose into which the flexible cannula extends; and the forehead, over which the exhaust tube extends in certain of the claims.

In placing these body parts in the preamble of the claims, the Applicants were attempting to provide an appropriate antecedent basis for later recitations in the claims that related to the positioning of the various parts of the invention relative to the body parts mentioned. As such, the Applicants believe that these recitations were not objectionable under Section 101.

In reviewing the Examiner's rejection, it appears the Examiner's primary objections related to the use of the body parts within the preamble of certain of the claims. To help address the Examiner's concerns, the Applicants have, in this Amendment, removed the body part recitations from the preamble of the claim, but has maintained them in other places in the claims.

The Applicants submit that this is perfectly acceptable within the rules of practice, and does not run a foul of Section 101. To support the Applicants' belief, the Applicants direct the Examiner's attention to Exhibit A. Exhibit A comprises samples of issued patents having claims that include recitations of body parts. These claims are pertinent as, just in the present invention, it is believed by the Applicants that the patents listed in Exhibit A do not make any attempt to claim the body parts listed in the claims, but rather, recite the presence of certain body parts as locators, to better describe particular parts of the various devices being claimed.

Exhibit A is not an inclusive list. It does not include all of the patents that recite a body part within a claim. The Applicants believe that such a list would be too extensive to include, for in the Applicants' limited search, they found 1,338 issued patents that included both of the terms "nose" and "mouth" within a claim.

Turning now to the patents contained with Exhibit A, it will also be noted that many of the patents appeared to have been examined by the Examiner's art unit, as the Examiner's supervisor, Henry Bennett, is listed as a primary Examiner on several of the patents shown in Exhibit A.

For the reasons set forth above, the Applicants submit that the Examiner's objections under Section 101 have either been rendered moot by the amendment made to the claims, or alternately, were rendered moot due to the impropriety of the rejections.

III. REJECTIONS UNDER SECTION 112

In the Official Action, the Examiner objected to Claims 1, 21, 30, 34-37 and 39 under Section 112.

In particular, the Examiner believes that the claims contain subject matter that was not described in the Specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. The Examiner believes that no support exists for terms such as "flexible cannula", "middle portion", "a second flexible cannula", a "first cannula to resist a movement of the first cannula" [that was] moved by the user"; and "a second inspiratory port being sized for slideably receiving the second cannula... of the second cannula when not being moved by the user".

Contrary to the Examiner's assertion, the Applicants believe that all of the materials above are described within the Specification, and are contained within the Specification in a manner that would enable one reasonably skilled in the art to appreciate the presence of these elements.

In this regard, the Examiner's attention is first directed to lines 17-22 of page 24, and lines 1-13 of page 25. This section of the application (as amended by the instant Response) is set forth below.

> "The first and second nasal cannulas 180, 184 are generally flexible pieces of respiratory tubing used with anesthesia devices. The first nasal cannula 180 has a source end 179, ~~and~~ a patient end 181, and a middle portion 193 disposed between the source end 179 and the patient end 181. The second nasal cannula 184 has a source end 183, ~~and~~ a patient end 185, and a middle portion 195 disposed between the source end 183 and the patient end 185. The source end 179 of the first nasal cannula 180 is connected to the patient end 171 of the first patient connector 172 of the mask connector 170. The source end 183 of the second nasal cannula 184 is connected to the patient end 173 of the second patient connector 174 of the mask connector 170. The inspiratory gas coming from the first patient connector 172 of the mask connector 170 enters the source end 179 of the first nasal cannula 180 and exits through the patient end 181. The inspiratory gas coming from the second patient connector 174 of the mask connector 170 enters the source end 183 of the second nasal cannula 184 and exits through the patient end 185.
>
> The first and second nasal cannula 180, 184 extend through the first and second inspiratory gas ports 121, 122 of the anesthesia mask 112 such that the patient ends 181, 185 of the nasal cannulas 180, 184 are under the crown member 132. The first and second inspiratory gas ports 121, 122 can be sized to form a snug fit with the first and second nasal cannula 180, 184 such that the user can move the cannula 180, 184 to place the patient ends 181, 185 in a desired position within the crown member 132 for delivery of inspiratory gas to the patient.
>
> As best shown in Figs. 5B and 6B, the patient ends 181, 185 of the nasal cannulas 180, 184 extend through the gas inspiratory ports 121, 122 of the crown portion 132."[1]

[1] The underlining and strikeout show amendments made in this Response

Turning to the above excerpt from the application, you will notice that it first states that "the first and second nasal cannulas 180,184 are generally *flexible* pieces of respiratory tubing used with anesthesia devices" (emphasis added). This sentence clearly discloses the fact that the tubes are flexible.

The next two sentences recited, prior to editing, that the first nasal cannula had a source end 179 and a patient end 181. It also recited that the second nasal cannula 184 had a source end and a patient end 185.

With this amendment, the Applicants have also added that the first and second nasal cannulas include middle portions 193, 195 respectively, that are disposed between the source end and the patient end.

Although the term "middle portion" was not used *per se* in the application as originally filed, the Applicants submit that a middle portion is clearly disclosed.

Your attention is now directed to Exhibit B, that comprises an excerpt from the Merriam Webster Collegiate Dictionary (10th Edition), and more particularly, to the dictionary's definition of "middle". The dictionary defines middle as 2: being at neither extreme, and also defines it as 1: a middle part, point or position [and] 4: something intermediate between extremes.

In the instant context, the source end 179 and patient end 181 are the "extremes" of the first nasal cannula. It follows, therefore, that the middle portion 193 of the first cannula is that portion of the cannula 180 that is disposed between the two extremes of the cannula, namely, the source end 179 and the patient end 181.

The same logic applies with respect to the second nasal cannula 184.

Turning now to Fig. 4B, it will be noted that the first and second cannulas, 180 184 are clearly shown as having middle portions 193, 195 respectively, that exist between their respective ends. As the disclosure of an application includes all of the subject matter within the originally filed application, including the Specification, Claims, Abstract and Drawings, the Applicants submit that a middle portion was, and always has been shown in the application, and as such is, (and was when filed), disclosed in a manner to enable one skilled in the art to understand the invention.

The additional clauses added by the Applicants relating to the middle portion add no new matter, but rather, do little more than commit to prose that which had already been disclosed in picture and logic.

In summary, the Applicant believes that the middle portion, while always disclosed explicitly, is now, with the amendment, disclosed more explicitly.

Turning back to the same section, the Applicant submits that the quoted passages set forth above also clearly disclosed the presence of a second cannula, (Claim 35), and a first and second flexible cannula (Claim 36).

The Examiner also believes that in Claims 36 and 37, terms such as "first cannula to resist movement of the ... moved by the user ... a middle portion, second inspiratory port being sized for slideably receiving the second cannula ... of the second cannula not being moved by the user. ," were not fully disclosed in the Specification.

Contrary to the Examiner's belief, the above recitations are fully supported and disclosed in the Specification.

The Examiner's attention is directed to the excerpt below taken from the application, at

page 22, lines 20-22, and page 23, lines 1-6.

> The first and second inspiratory gas ports 121, 122 are generally circular openings in the crown member 132 that are sized for snugly, but slideably receiving the inspiratory gas line 120 so that the inspiratory gas line can extend there through to deliver inspiratory gases directly to the patient's nose within the anesthesia face mask 112. Fig. 4B shows an inspiratory gas line 120 which includes a source line 152; a line splitter 156; first and second intermediate lines 160, 164; a slide member 162, a mask connector 170 and first and second nasal cannula 180, 184. The source line 152 is a generally cylindrical gas line used in anesthesia devices that includes a source end 151 and a patient end 153. The source end 151 is connected to an inspiration gas source 150, and the patient end 153 is connected to the line splitter 156.

The excerpt above clearly states that the first and second inspiratory gas ports 121, 122 are sized for *snugly but slidably* receiving the inspiratory gas line 120, so that the inspiratory gas line can extend therethrough.

The Examiner's attention is now directed to the excerpt below, that is taken from the Specification at page 25, lines 6-15.

> The first and second nasal cannula 180, 184 extend through the first and second inspiratory gas ports 121, 122 of the anesthesia mask 112 such that the patient ends 181, 185 of the nasal cannulas 180, 184 are under the crown member 132. The first and second inspiratory gas ports 121, 122 can be sized to form a snug fit with the first and second nasal cannula 180, 184 such that the user can move the cannula 180, 184 to place the patient ends 181, 185 in a desired position within the crown member 132 for delivery of inspiratory gas to the patient. As best shown in Figs. 5B and 6B, the patient ends 181, 185 of the nasal cannulas 180, 184 extend through the gas inspiratory ports 121, 122 of the crown portion 132. As the patient end 181 185 of the nasal cannulas 180, 184 within the nares N of

> the nose Z of the patient P, the anesthesia gas is deposited directly into the nares N for inhalation by the patient.

This section clearly states that the first and second nasal cannula 180, 184 extend through the inspiratory gas ports 121, 122, and that the inspiratory gas ports are sized to form a snug fit with the first and second cannulas such that the user can move the cannula to place the patient end in a desired position within a crown member.

The "snug but slidable" description of the size relationship between the gas ports and cannula clearly discloses that the cannula and gas ports are sized relative to each other, to have a "loose" enough fit so that the cannulas can be slid within the gas port to change the amount of length of the cannula that is within the dome of the mask; while still retaining a "snug" enough fit between the cannula and the gas port so that the cannula and the gas port will tend to retain their relative positions within the gas port in the absence of a force (such as that exerted by the user) that serves to either slide the cannulas in the gas port, to either increase or decrease the length of the cannula disposed within the interior of the dome portion of the face mask. As such, the Applicants submit that they have complied fully with the written description requirement, as all of the materials recited in the claims are clearly disclosed within the Specification.

The Examiner later suggests that in paragraph 6 of the Official Action, that the middle portion is not disclosed in the original disclosure. For the reasons set forth above in connection with the Applicants' disclosure of what constitutes a "middle portion", the Applicants submit that a "middle portion" is fully disclosed now in the amended Specification, and was fully disclosed in the originally filed application.

IV. THE SUBSTANTIVE REJECTIONS

A. Overview of the Examiner's rejections made in the 25 January 2006 Official Action.

In the Official Action, the Examiner rejected all of the claims under Section 103. To support the rejection, the Examiner employed a combination of references for each rejection.

The art relied on by the Examiner included references such as Blasdell, U.S. Patent No. 5,419,317; Schauweker, U.S. Patent No. 2,462,005; Kwok, U.S. Patent No. 6,112, 746; Vanuch, U.S. Patent No. 5,243,708 and Muto, U.S. Patent No. 4,454,880.

The above mentioned references were all originally used to reject the claims in the first Official Action.

As stated at the interview, none of the Blasdell, Schauweker, Kwok, Vanuch or Muto disclosed or suggested the use of an inspiratory gas line for delivering inspiratory gases, wherein the inspiratory gas line of a patient end that was configured for insertion into the naris.

In the rejections, the Examiner also cited additional references not previously seen, namely McAuley, U.S. Patent Application No. 2003/0094178, and Barnett, U.S. Patent No. 6,412,488.

McAuley was cited primarily because of its alleged teaching of an inspiratory gas provided within each nostril of a patient through a nasal cannula. Barnett was recited primary because of its alleged teaching of a nasal face mask assembly having an exhaust tube in communication with the mask at an elbow connection, wherein the exhaust tube extended over the forehead of the patient.

B. The Applicants' Invention and the Claims As Amended.

As discussed in the Response to the last Official Action, one of the features of the Applicants' invention is that it includes a flexible cannula having an outside portion disposed outside the dome, a patient end inserted into the naris of a patient, and the middle portion that is adjustably positionable with respect to the face mask, to permit the user to adjust the position of the cannula. This position can be adjusted in a manner that increases or decreases the length (amount) of the cannula within the dome portion.

By enabling the user to vary the length of the cannula within the dome portion, he can adjust the length of the cannula to fit noses of different sizes. Further, the flexible nature of the cannulas, when coupled with their "snug but slidable" engagement with the gas ports allows the first and second cannulas to be independently adjustable with respect to each other in those embodiments employing a first and a second cannula. This independent adjustability further enhances the medical practitioner's ability to vary the position fo the two cannulas to better fit the particular patient, and also better enables the practitioner to position the first and second cannulas independently of each other.

Additionally, the flexibility of the cannula permits the user to manipulate the position of the cannula so that the user (usually a medical or dental practitioner) can better adjust the lateral position of a cannula to better fit the nose of the patient into which the cannula is being inserted.

As discussed in the last Official Action, noses vary in length, width and other factors. Importantly, noses vary in the width of the columella that separates the nose into two nostrils (naris). Because the columella of patients differ widely, the Applicants have found that it is very helpful to be able to adjust the relative width and separation of the cannulas inserted into the nostril to ensure that the nostril-engaging patient ends of the inspiratory port are properly

positioned within the nostril. This variable positioning cannot be accomplished with either the Fisher device that was discussed in the last Official Action, or with the devices shown in the McAuley or Barnett references disclosed in this Official Action.

Additionally, the Applicants' arrangement also permits the length of the cannula within the interior of the face mask to be varied. The Applicants' design enables the practitioner to insert a relatively long portion of the cannula interiorly of the face mask to ensure that the cannula is inserted deeply enough within the naris of the patient to help ensure that gas flowing from the cannula is received within the body of the patient. Alternately, the practitioner can pull the cannula out to reduce the length of the cannula within the dome portion, so that only a short length of the cannula is contained within the interior of the mask. A shorter length of cannula placed inside the mask may be appropriate if the patient has a large or long nose, that is placed close to the dome. In such a large-nosed patient, only a short length of cannula is necessary to have the cannula inserted at a proper depth within the naris. The "axial variability" of the Applicants' invention is not possible with the configurations shown in the prior art.

Another feature of the Applicants' invention is that it includes an exhaust port, elbow and exhaust tube arrangement that allows the exhaust tube it to pass over the forehead of a patient, rather than along side the patient. The advantage obtained by this feature is that masks having "side loading" tubes tend to be ergonomically disadvantageous to the practitioner operating on the patient.

Because many procedures are rather lengthy, practitioners (especially dentists, and oral surgeons) prefer to sit while performing a procedure on the patient. The side hanging hoses on masks, such as those shown in the prior art, force the oral surgeon to place herself in a position

where she can work on the patient while not interfering with the hoses. This causes the oral surgeon to position herself further away from the patient than she would prefer.

By contrast, one embodiment of the Applicants' invention employs an exhaust line that hangs over the forehead of the patient and over the patient's head, and then leads back to the anesthesia device. Through the Applicants' configuration, the oral surgeon does not need to "work around" the side hanging tubes. As such, the oral surgeon can get closer to the patient, and assume a more ergonomically correct position while operating on the patient.

C. *The Newly Cited Art*

In the prior response, it was pointed out that the prior cited references, including Fischer, U.S. Patent No. 4,248, 218; and Brekke et al,, U.S. Patent No. 4,151,843 did not disclose or suggest the applicant's invention, and that he applicant's claims were patentably distinguishable over these references.

As discussed above, none of the art cited in *this* Official Action, that was cited in previous Official Actions discloses or suggests the Applicants' flexible and adjustably positionable cannula, nor does the prior cited art disclose or suggest the Applicants' arrangement wherein the exhaust elbow and exhaust line arrangement is positioned to extend over the forehead of a patient. the newly cited prior art does not disclose or suggest these features either.

1. McAuley U.S. Patent Publication No. 2003/0094178

The McAuley reference actually shows two very distinct devices. The device shown in Figs. 2 and 7 appears to comprise a pair of nasal tubes 32, 33 coupled together by a "Y"

connector 31. The McAuley nasal tube device 30 appears to be a stand alone device, that is used by itself, rather than being used with a mask. Nothing in the McAuley patent discloses that the device shown in Fig. 2 is useable in connection with a mask.

The second embodiment of McAuley's device is best shown in Figs. 11-16. Turning now to Fig. 11, one of the single tubes 65 is used. Tube 65 terminates at an end (close to the end of line 62). A mask 61 (referred to as a nasal sealing flap) is provided, and a pair of cannulas, 63, 64, extend through the mask.

As you will note from the drawings, the length of the cannula 63, 64 are rather short. Additionally, there is little length of cannula between the mask and the end of tube 60. It is also note worthy that the cannula 63, 64 are designed for "inspiratory gas" to be delivered to a patient, and that there is no feature in McAuley's mask that would provide any evacuation of gas.

Most importantly, McAuley's cannula 63, 64 are not adjustably positionable with respect to the mask. In this regard, the Examiner's attention is directed to paragraph 59 of the McAuley reference that is shown at page 4, col. 2. McAuley states:

> "The nasal device comprises the nasal sealing flap [mask] 61 connected by appropriate means to a nasal member 62 that terminates in at least one nasal cannula, although in the preferred form two cannulae 63, 64 are provided, one for each of the patient's nares. The *flap 61 and cannulae 63,64 may be integrally formed or the flap 61 may be attached about the cannulae 63, 64 (by appropriate means, such as gluing) after the cannulae have been formed. Furthermore, the cannulae 63, 64, flap 61 and nasal member 62 may all be integrally formed by injection molding or the like methods.* The cannulae 63, 64 extend through the proximate end of the flap 61, so that in use, upon placing the flap about the patient's nose the cannulae extend into the nasal cavities of the patient's nose. The other end of the nasal member 62 is connected, again by appropriate fixing means, such as by friction fit, snap fit, gluing, welding, threading or the like, to a nasal tube 65." (Emphasis added)

As will be appreciated, the integral molding of the cannulae 62, 63 and mask 61; or alternately, the gluing of the cannulae 63, 64 to the mask 61, in McAuley will fixedly position the cannulae 62, 63 with respect to the mask 61. As such, the cannulae cannot be slid with respect to the mask, to make the portion of the cannulae inside the mask either longer or shorter, to adjust to patients having noses of different sizes. Additionally, from the length of the cannulae shown in the drawings, the cannulae 63, 64 do not appear long enough to provide much lateral adjustability.

In summary, nothing in McAuley discloses or suggests providing an adjustably positionable cannula in connection with the face mask system, as recited in Applicants' claims. Nor does anything in McAuley disclose or suggest providing a mask system having an exhaust valve, wherein the exhaust valve is placed over the forehead of the patient, that is also recited in the Applicants' claims.

2. Barnett U.S. Patent No. 6,412,488

The Barnett reference was cited primarily against the feature recited in Applicants' claims that relates to the exhaust tube being positioned to extend over the forehead of the patient. (See Applicants' Claims 24 and 38). Turning now to Barnett at Fig. 1A, it will be noticed that Barnett shows a mask that appears to have a soft face-engaging portion 32, and gas port 76 that forms an elbow, and terminates the conduit receiver 36, that can be attached to a tube of some sort.

Barnett describes the area shown as 58 as being the upper portion of the face mask. Therefore, it appears that the conduit 36 may extend generally parallel to the nose, and would open upwardly to a position adjacent the forehead.

However, an important distinction between Barnett and the Applicants' claimed invention exists. This distinction is the conduit 36 is described in Barnett as being an *inspiratory* conduit, rather than an *evacuation or exhaust* conduit. As such, Barnett does not disclose or suggest the use of an exhaust or evacuation conduit that is positionable to extend over the forehead. Additionally, Barnett does not disclose or suggest the use of flexible cannula, as no cannulas that are insertable into the naris of a patient are shown or suggested anywhere within the Barnett device.

V. AMENDMENTS TO THE CLAIMS

In this Response, the Applicants have amended their claims to more clearly recite those differences, described above, that patentably distinguish the Applicants' invention from the art of record.

Turning now to Claim 1, it will be noted that it has been amended to now recite that the dome [of the face mask] includes a gas port, and that the gas port of the face mask is sized to slideably receive the flexible cannula for permitting the user to move the cannula relative to the face mask and gas port to enable a user to place an end of the flexible cannula in a desired position within the naris of the patient.

Claim 21 has been amended similarly to Claim 1 and includes the recitation described above in connection with Claim 1.

As alluded to above, this feature is neither disclosed or suggested in any of the art of record, as McAuley neither discloses or suggests such an adjustably positionable cannula that is placeable within the naris of a patient. Certainly, the fixedly position cannula of McAuley cannot

disclosure or suggest it.

The Examiner's attention is next directed to Claim 24. Claim 24 recites the combination of a face mask, an exhaust port, an inspiratory port, an inspiratory gas line, an elbow, and an *exhaust line*, wherein the exhaust line is positioned by the elbow to extend over the forehead of a patient. As discussed above, Barnett does not disclose or suggest such a device. To the contrary, Barnett discloses the use of an inspiratory line that extends over the forehead, rather than an exhaust line that is claimed by the Applicants.

The Examiner's attention is next directed to Claim 25. Claim 25 has been amended to include a recitation similar to that discussed above in connection with Claim 1. Even though the Applicants believe that Claim 25 is allowable for no other reason than its dependency from allowable Claim 24, the Applicants submit that Claim 25, on its own, includes additional recitations that render it patentably distinguishable from the art of record, regardless of whether the Examiner would find Claim 24 to be allowable.

The Examiner's attention is next directed to Claim 30. Claim 30 has been amended to recite that the middle portion of the flexible cannula is slideably but snugly received in the inspiratory port to extend through the dome portion.

This snug but slideable connection between the cannula and the dome portion gives the flexible cannula and the user the ability to adjust the length of the cannula within the dome portion, to thereby enable the cannula to be positioned to better fit the patient, than a device wherein such adjustability was not achievable. Nowhere is this disclosed or suggested in the art of record, as the art cited by the Examiner, including McAuley and Fisher, that contain naris-insertable cannulas, do not disclose or suggest a nasal insertable cannula that is adjustably

positionable.

This "slideably but snugly" feature has also been added to Claim 36. Although Claim 36 is believed to be allowable based solely upon its dependency from allowable Claim 1, this additional recitation provides a further patentably distinguishing recitation that makes Claim 36 allowable, even if the Examiner were to find that Claim 1 (the claim from which it depends) is not patentable. This "slideable but snugly received" feature of the cannula is also incorporated into amended Claim 37.

The Examiner's attention is next directed to Claim 38. Claim 38 is similar to Claim 24, as both recite the presence of a face mask, inspiratory gas line, a vent, an exhaust port, an elbow, and an exhaust line, wherein the exhaust line is positioned by the elbow to extend over the forehead of the patient. For the same reasons as those discussed in connection with Claim 24, the Applicants believe that Claim 38 is patentably distinguishable over the art of record.

Claim 39 depends from Claim 38, and includes a recitation relating to the device including a flexible cannula that is slideably but snugly received by, and extends through an inspiratory port in the face mask. Even if the Examiner were to believe that Claim 38 is not patentable, these features recited within Claim 39 patentably distinguish it from the art of record, and argue strongly for its allowance over the art of record.

The Examiner's attention is next directed to Claim 40, which depends from Claim 1. Claim 40 recites that the inspiratory gas port of the face mask is sized to slideably but snugly receive the flexible cannula relative to the face mask and gas port, to enable the user to adjust the length of the cannula within the inside air space so that the cannula is properly positioned within the naris of a patient. This feature amplifies the distinctions discussed above between the

Applicants' face mask and cannula arrangement and that disclosed by the prior art. Although the Applicants believe that Claim 40 is allowable by virtue of its dependency upon allowable Claim1, the Applicants also submit that Claim 40 is patentable in its own right, even if the Examiner were to find that Claim 1 was not patentable.

Finally, the Examiner's attention is directed to newly added Claim 41. Newly added Claim 41 recites that the device includes a face mask, an inspiratory gas line having a patient end portion, and a face mask. The patient end portion of the inspiratory gas line includes a source end, a patient end disposed within the dome portion and being configured for being received within the naris of a patient for delivering inspiratory gas to the naris of a patient. Additionally, the patient end portion includes a middle portion that extends through the dome portion, and has a length disposed within the dome portion, wherein the length of the middle portion disposed within the dome portion is variable by the user.

Nowhere is this variable length cannula and mask arrangement disclosed or suggested by any of the art of record.

In summary, the Applicants have amended their claims to recite those differences that help to further distinguish the Applicants' invention from the art of record. For the reasons set forth in connection with the Examiner's Section 112 rejections, all of the materials that have been added by this Amendment are clearly disclosed by the application, and were disclosed by the Applicants at the time of filing. As such, nothing within the claims adds anything to the claims that could be construed as comprising new matter.

VI. SUMMARY

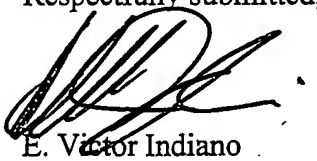
Applicants believe that the present application, as amended, is in condition for allowance. Re-examination and reconsideration, culminating in the allowance of all claims, in due course, is respectfully requested.

If the Examiner has any questions relating to this Amendment, or would like to discuss any issues about this case with the Applicants' Attorney, she is respectfully requested to contact the Applicants' Attorney, E. Victor Indiano, at (317) 822-0033, or via e-mail at Vic@IPLawIndiana.com.

VII. REQUEST FOR EXTENSION OF TIME

If necessary, Applicants request that this Response be considered a request for an extension of time for a time appropriate for the response to be timely filed. Applicants request that any required fees needed beyond any submitted with this Response, be charged to the account of **E. Victor Indiano, Deposit Account Number 50-1590**.

Respectfully submitted,



E. Victor Indiano
Reg. No. 30,143

Enc: Marked up copy of Fig 4B and a replacement sheet of drawings containing Fig 4B and labeled as a "REPLACEMENT SHEET"

Exhibit A– Copies of issued patents showing the recitation of "body parts" within an allowed and issued claim.

Exhibit B– An excerpt from the Merriam-Webster New Collegiate dictionary defining "Middle"

cc: Kevin Burrow
Dennis Irlbeck
John Moenning
Thomas McGrail

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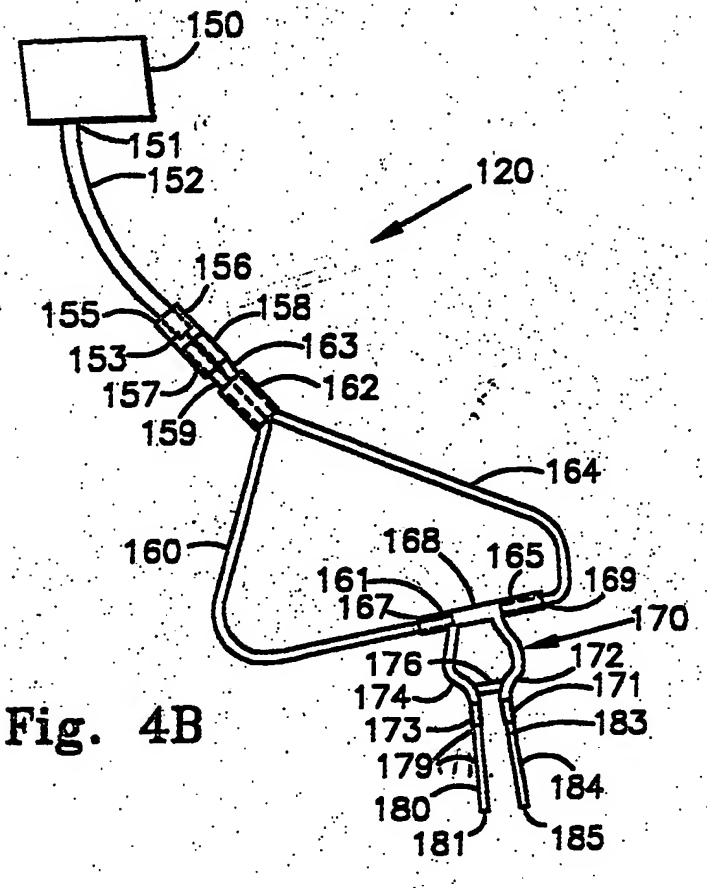

Fig. 4B

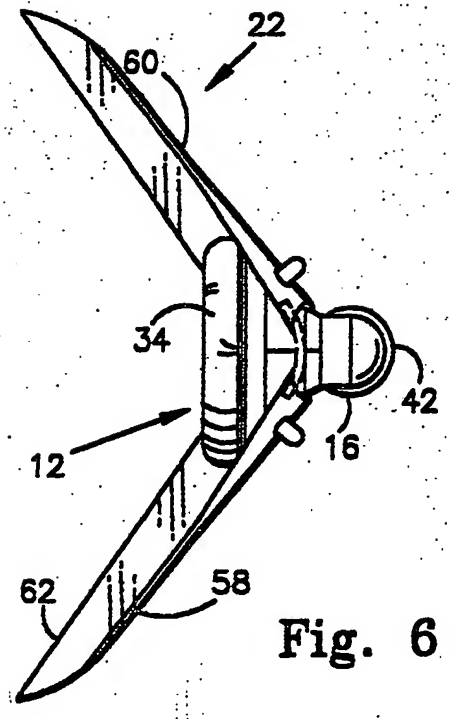

Fig. 6

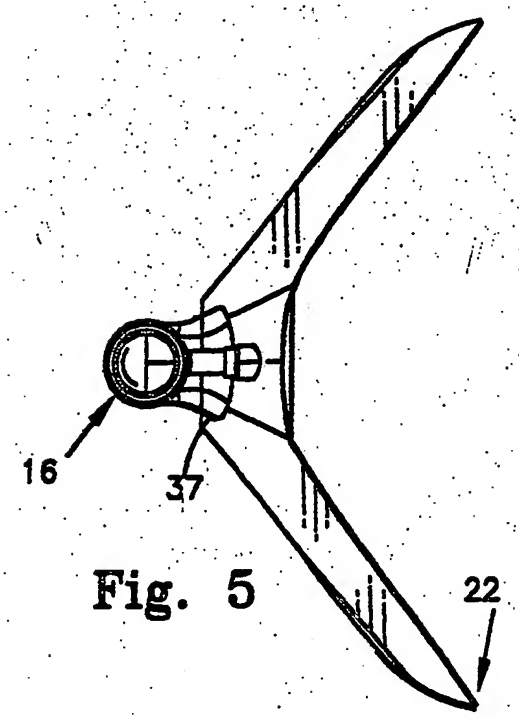

Fig. 5

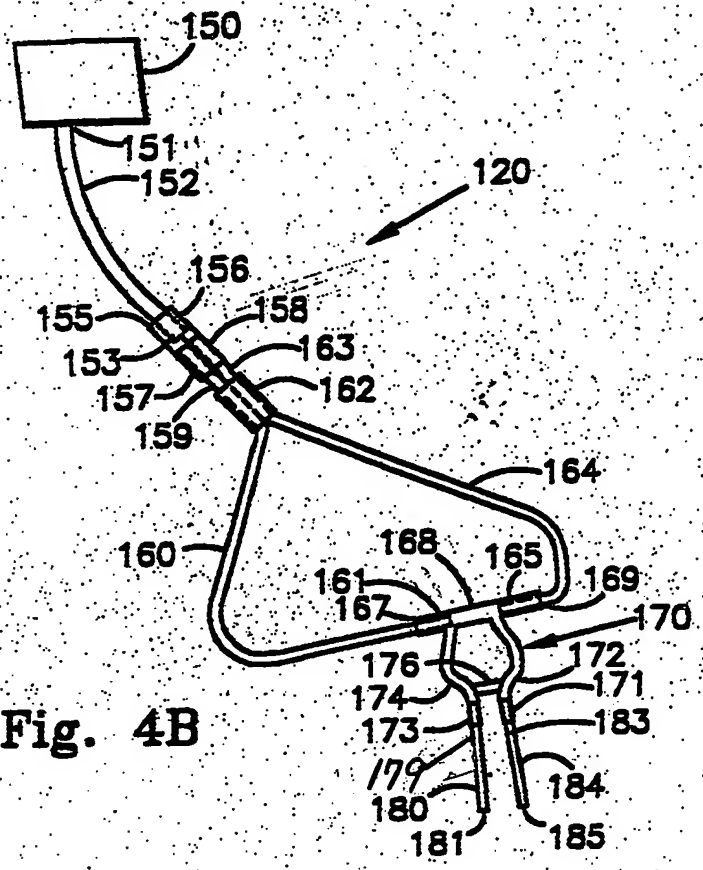

Fig. 4B

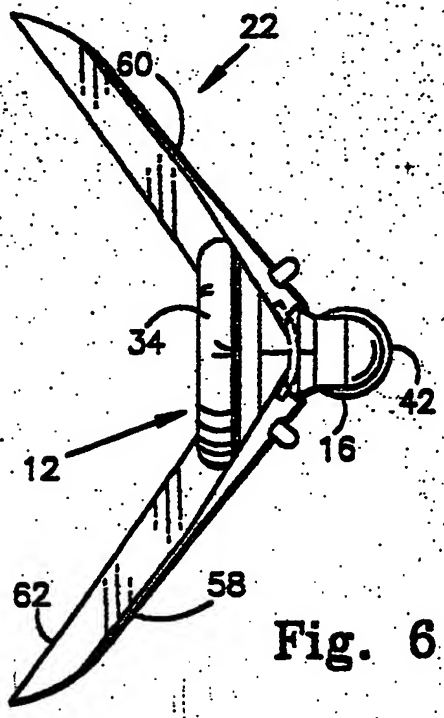

Fig. 6

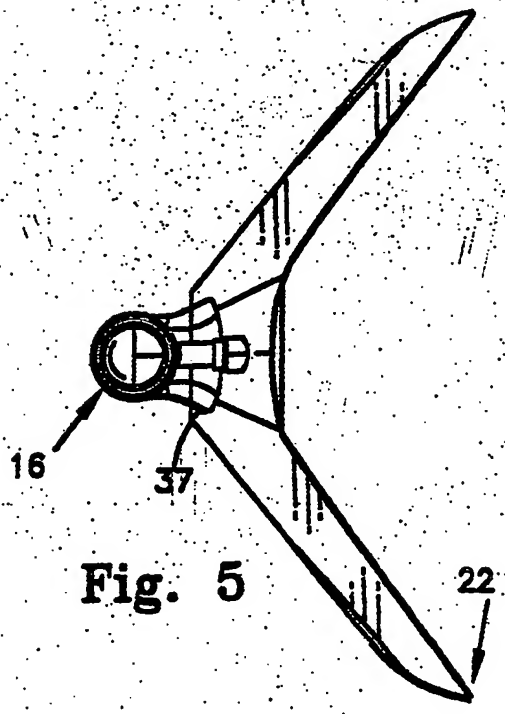

Fig. 5

EXHIBIT A

Samples of Issued Patents Whose Claim Include Recitations of Body Parts

US007017577B2

(12) **United States Patent**
Matich

(10) **Patent No.: US 7,017,577 B2**
(45) **Date of Patent: Mar. 28, 2006**

(54) **FACE MASK WITH SEAL AND NEUTRALIZER**

(76) Inventor: **Ronald D. Matich**, P.O. Box 2541, Baxter, MN (US) 56401

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 353 days.

(21) Appl. No.: **10/052,532**

(22) Filed: **Jan. 18, 2002**

(65) **Prior Publication Data**

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(51) **Int. Cl.**
A62B 18/08 (2006.01)

(52) **U.S. Cl.** **128/206.14**; 128/206.19; 128/206.25

(58) **Field of Classification Search** 128/206.25, 128/206.14, 205.27, 205.28, 205.29, 206.12, 128/206.15, 206.21, 206.23, 206.24, 201.17, 128/206.17, 201.25
See application file for complete search history.

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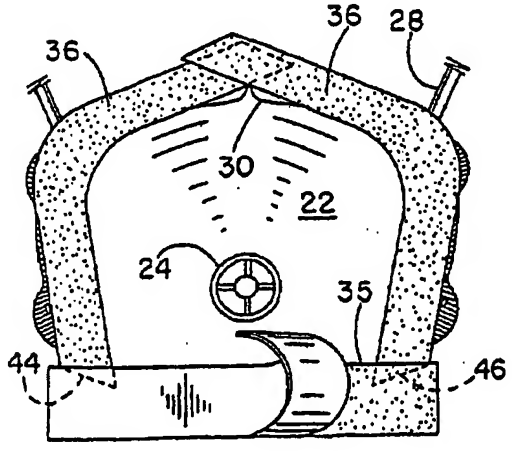
Primary Examiner—Mital Patel

(57) **ABSTRACT**

A sealed face mask. The face mask may be a common paper face mask or a more technically complex gas mask. The face mask includes a periphery. The periphery includes a seal that surrounds the nostrils and the mouth and that sticks to the skin of the face. The adhesive of the seal may be a skin friendly adhesive or a skin unfriendly adhesive. With the skin unfriendly adhesive, the adhesive includes a strength sufficient to remove a first layer of skin from the face when the seal is pulled from the face. The seal includes a strip that may be elastomeric. The periphery of the face mask may be elastomeric. The face mask includes a neutralizing agent to minimize harmful effects of substances passing through the face mask. Further disclosed is a method for fixing the face mask to the face. Also disclosed are sealing strips for the lower ends of the legs of a pair of pants, sealing strips of the outer ends of the sleeves of a shirt, and sealing strips for other articles of clothing.

2 Claims, 13 Drawing Sheets



Because of this the skin barrier according to the invention is not only suited as sealing and adhesive gasket for ostomy pouches and other ostomy closure means, but also for bandaging purposes where skin, mucous membranes or wounds are to be protected against the immediate surroundings such as intestinal, wound or glandular secretions or again bacterial attack, the action of the air, evaporation, light, impact and pressure. If the skin barrier is to be used in connection with real bandages change of these may take place without disturbing the surface of the skin or wound since the skin barrier is retained on the skin at the change, and moreover it will in itself limit bandage changes to a minimum. The material is skin and wound friendly and because of the elastic properties it may in many cases draw edges of wounds together and render superfluous the use of clips, which may give a less visible wound healing than would otherwise be the case. By use around movable parts of the body, e.g. joints, or on soft parts of the body, which for instance are apt to form folds, the mobility is preserved and the skin barrier follows the movements. The skin barrier seals well around protruding part of the body, e.g. ostomies.

As elastomer there is used as mentioned styrene-olefin-styrene block copolymers. They are A-B-A block copolymers having polystyrene end blocks which are thermodynamically incompatible with the polyolefin rubber middle blocks. Consequently there is phase separation in the solid state. The polystyrene constitutes about a third of the molecule and hard polystyrene domains are therefore a kind of discontinuous phase distributed in a rubber matrix. The hard areas constitute the physical cross-links which bind the ends of the molecules together to a network reminding of that formed by a conventional vulcanized rubber (caoutchouc). Since the high cohesive strength of the block copolymer originates from the physical cross-links (instead of from the chemical cross-links as in vulcanized materials) it is easy to work. In comparison with conventional rubbers the styrene-olefin-styrene block copolymers have low molecular weights, of the A-blocks around 2000–100,000 and of the B-blocks around 25,000–200,000. The content of styrene units is normally below 40%. These block copolymers have two glass transition temperatures, one below, the other considerably above room temperature.

The aliphatic blocks may be based on isoprene, butadiene, other short chain alkadienes or alkenes such as mixtures of ethylene and butylene, or polyisobutylene. It has been found according to the invention that the elastomer particularly advantageously is a styrene-isoprene-styrene block copolymer. Very suitable is the material sold under the registered trade mark "Cariflex" Tr-1107, which contains about 28% by weight styrene units.

The proportions of the several components may vary within rather wide limits. The amount of the elastomer, however, is normally somewhat higher than in the material known from U.S. Pat. No. 4,231,369 and according to the invention constitutes 10–40% by weight of the adhesive layer, preferably 20–40%. According to the invention the composition of the adhesive layer expressed in % by weight may be: elastomer 10–40%, preferably 20–40%; tackifier resin 15–45%, preferably 30–40%; plasticizer for the two domains of the elastomer as defined 2–12%, preferably 8–12%; antioxidant 0.5–2.5%; oily extender 0–25% and hydrocolloid 10–55%, preferably 20–40%.

An especially preferred composition is about 25% styrene-isoprene block copolymer (notably one containing about 20% styrene unites, "Cariflex" ® TR 1107), about 35% tackifier resin, about 9% dioctyl adipate, about 1% antioxidant and about 30% sodium carboxymethylcellulose.

FIGS. 1B, 7A 7B, 8B, and 9 show an uninterrupted endless seal 12 that completely surrounds the nostrils and mouth. FIGS. 5A and 5B show the neutralizing agent 66 extending from a top side to a bottom side of the covering 16 and from a right side to a left side of the covering 16 such that any air passing through the covering 16 confronts the neutralizing agent 66.

Thus since the invention disclosed herein may be embodied in other specific forms without departing from the spirit or general characteristics thereof, some of which forms have been indicated, the embodiments described herein are to be considered in all respects illustrative and not restrictive. The scope of the invention is to be indicated by the appended claims, rather than by the foregoing description, and all changes which come within the meaning and range of equivalents of the claims are intended to be embraced therein.

I claim:

1. A sealed face mask, comprising:

a) a covering for the nostrils and mouth;

b) wherein the covering includes a periphery completely surrounding the nostrils and mouth, wherein the periphery is structured to extend from a first position on the bridge of the nose above the nostrils to the right side of the nose, from said right side of the nose to a position on the front of the face beyond the right side of the mouth, from said position beyond the right side of the mouth to a position on the front of the face below the lower lip and on the front of the chin, from said position below the lower lip to a position on the front of the face beyond the left side of the mouth, from said position beyond the left side of the mouth to the left side of the nose, from said left side of the nose back to said first position on the bridge of the nose such that the nostrils and mouth are completely surrounded;

c) wherein the covering comprises a portion projecting beyond the mouth, with the portion projecting beyond the mouth being within the periphery and being convex relative to an exterior of the portion;

d) wherein the covering is structured to permit air into and out of the covering;

e) wherein the covering is structured to minimize a flow of substances into and out of the covering;

f) a neutralizing agent engaged to the covering where the covering is structured to permit air into the covering to maximize the chances that substances passing through the covering are rendered less harmful by the neutralizing agent, with the neutralizing agent extending from a top side to a bottom side of the covering and from a right side to a left side of said covering such that any air passing through said covering confronts the neutralizing agent;

g) wherein the neutralizing agent comprises activated charcoal;

h) a seal on an entirety of the periphery, with the seal being an uninterrupted endless seal adapted to completely surround the nostrils and mouth, wherein the seal includes an adhesive that sticks to skin to minimize an amount of substances that access the nostrils and

US007028688B1

(12) **United States Patent**
Grove et al.

(10) **Patent No.: US 7,028,688 B1**
(45) **Date of Patent: Apr. 18, 2006**

(54) **OPERATIONALLY ADAPTABLE CHEMICAL-BIOLOGICAL MASK**

(75) Inventors: **Corey M. Grove**, Red Lion, PA (US); **Stephen E. Chase**, Jarrettsville, MD (US)

(73) Assignee: **The United States of America as represented by the Secretary of the Army**, Washington, DC (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 63 days.

(21) Appl. No.: **11/100,233**

(22) Filed: **Apr. 5, 2005**

(51) **Int. Cl.**
A62B 18/00 (2006.01)

(52) **U.S. Cl.** **128/201.25**; 128/201.22; 128/206.17; 128/206.15

(58) **Field of Classification Search** 128/201.22, 128/201.25, 205.25, 205.27, 205.29, 201.23, 128/206.17
See application file for complete search history.

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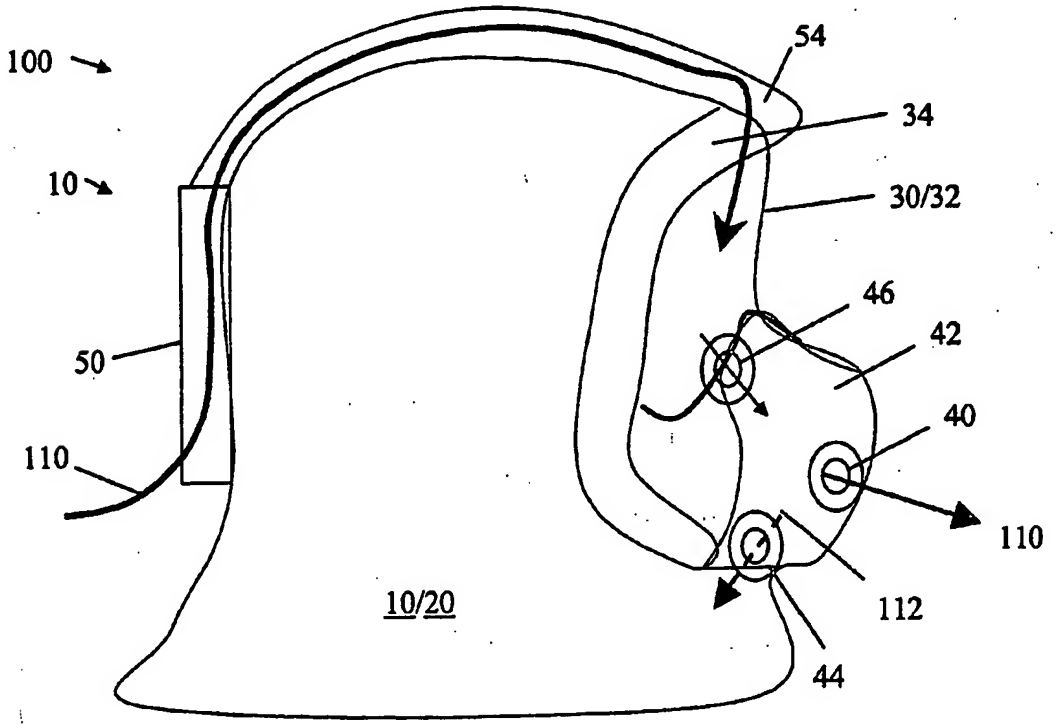
(74) *Attorney, Agent, or Firm*—Ulysses John Biffoni

(57) **ABSTRACT**

A chemical-biological protective mask having a weight distribution that imparts a balanced center-of-gravity to the wearer of the mask, and is adaptable for different operational requirements by adjusting or altering the air flow through the mask. The protective mask includes a head covering to fully cover the wearer's head including a hood, a face piece having a visor contoured to the wearer's face, ducting within the mask connected to a filtering system mounted at the rear of the head covering and a purge airflow through the hood. Additional side or front mounted filters can be added to provide either parallel or series filtration with the rear mounted filters. A blower system may also be used to impart an airflow into the mask and improve breathing resistance.

18 Claims, 9 Drawing Sheets



and into the mask face-piece **30**. Air is then drawn into nose cup **42** through inlet valve **46**, and discharged through air exhalation valve **40** in the nose-cup **42**, also using the small fan or blower system **60**. The addition of the small fan or blower **60** provides some overpressure to the face-piece **30** to improve protection and reduce the breathing resistance. The high surface area and low resistance of the rear-mounted filters **50** allows for the use of a fairly small blower unit **60**. Representative blowers **60** include for example, without limitation, the Micronel C301 fan manufactured by Micronel U.S. of Vista, Calif. Airflow **110** provided by the blower **60** should be sufficient for pressurization of the mask **100** and/or cooling to the wearer, with representative airflow being from about 0.5 CFM to about 5 CFM, including a preferred airflow of from about 1 CFM to about 2 CFM. As shown in previous embodiments, exhalation valve **40** may be closed to force exhaled air through purge valve **44** and provide a purge and overpressure airflow **112** to hood **20**.

In FIG. **7**, airflow **110** is pushed through the rear-mounted filters **50** into the mask face-piece **30** using a small head-mounted fan or blower system **60** while airflow **110** is also drawn through the side mounted filters **52** and ducted directly to face piece **30**. The air in the face piece **30** can then be drawn into the nose cup **42** through inlet valve **46**. In this configuration, airflow **110** can be balanced to provide enhanced protection and filtration capacity as well as reduced breathing resistance. Here again, as shown in previous embodiments, exhalation valve **40** may be closed to force exhaled air in the nose cup **42** out through purge valve **44** and provide a purge and overpressure airflow **112** to hood **20**.

Another alternative embodiment, as shown in FIG. **8**, uses an airflow **110** pattern that provides higher protection performance. After the airflow **110** is pushed through the rear-mounted filters **50** into the mask face-piece **30** using a small head-mounted blower system **60**, the airflow **110** bypasses the nose-cup **42** and is purged directly into the hood **20** using a secondary valve **48**. In this embodiment no nose cup inlet valve is required. In FIG. **8**, airflow **110** for breathing is drawn through the side mounted filters **52** only and is directed directly into nose cup **42**. Although filter capacity is not increased in this configuration, protection is significantly improved by purging both the face-piece **30** and hood **20**. A diverter **70** may be used to redirect the airflow from the blower **60** within the head covering **10**, such as redirecting the airflow **110** between the face-piece **30** and the hood **20** of the head covering **10**.

The airflow **110** pattern shown in FIG. **9** shows airflow **100** drawn through the side filters **52** and then the rear-mounted filters **50**, in series, then into the mask face-piece **30** using a small head-mounted blower system **60**. Air can then be drawn into the nose cup **42** through inlet valve **46**. Here again, exhaled air can be directed through an outlet valve **40** to the outside environment or optionally directed **112** into the hood **20** through purge valve **44** as overpressure to aid in purging the hood **20** by closing outlet valve **40**.

Alternative configurations allow for the incorporation of a head mounted blower and/or additional front mounted filters. This provides the wearer with options to tailor the protection and filter capacity to suit the mission. It is envisioned that the wearer could engage the filters collectively or as a primary and secondary filter option. It is also envisioned that the wearer could redirect blown air directly to the face piece or to the hood for additional cooling and protection. Unlike previously known mask systems, the present invention may be effectively adapted to utilize multiple filter configurations.

The chemical/biological protective mask **100** of the present invention provides a balanced system for dealing with contamination through improved center-of-gravity forces imparted onto the wearer that occurs with the adjustment of the weight distribution within the mask **100**. The present invention provides the wearer of protective equipment an expanded visual field-of-view, lower breathing resistance, improved protection and improved compatibility. Because much of the facial bulk is removed, the lens or visor system can be expanded to improve visual field-of-view. Compatibility with external sighting systems and rifle firing is improved since the filters have been moved from the front of the mask. A larger filter surface area provides for lower breathing resistance and the potential for higher filter capacity. Protection is also improved by removing the weight of the filters from the face, which minimizes torque of the face-piece and allows for use of a softer seal material. Finally, alternative airflow patterns allow the mask to be tailored for particular applications, and the mask provides the ability for the user to modify the airflow as required. For example, the mask can be adjusted so that exhaled air is directed to the hood for over-pressurization rather than being exhaled to the outside environment.

The foregoing summary, description, and examples of the present invention are not intended to be limiting, but are only exemplary of the inventive features which are defined in the claims. Alternative materials and configurations to those described herein for the present invention may be used.

What is claimed is:

1. An operationally adaptable chemical-biological protective mask, comprising:

a head covering effective for fully covering the wearer's head, wherein the rear and top sections of said head covering comprises a hood and the front of said head covering comprises a face piece; wherein said face piece has at least one visor effective for providing a visual field of view to the wearer, said face piece is securely attached to said hood, and wherein said face piece includes a face seal for sealing the face piece to the wearer's face;

a nose cup positioned within said face piece to fit over the mouth and nose of the wearer, said nose cup having an inlet valve, an exhalation outlet valve comprising a valve which can be closed by the wearer, and a purge valve for directing air into said hood when said outlet valve is closed by the wearer;

an air supply port positioned at the rear of said hood for permitting outside air to be supplied to the inside of said head covering;

one or more rear filters mounted in combination with said rear mounted air supply port, wherein said one or more rear mounted filters cleanse air flowing into said head covering; and,

ducting adjacent to said head covering and connecting said rear-mounted air supply port to said face piece, said ducting providing a conduit for filtered air from said rear mounted supply port into said face piece.

2. The protective mask of claim 1, further comprising one or more side filters mounted on one or more side air supply ports, with each having ducting connecting said side filters to said face piece so that additional outside air is supplied directly to said face piece through said one or more side filters, so that said rear mounted filters and said side mounted filters act in parallel.

US007028689B2

(12) **United States Patent**
Martin et al.

(10) **Patent No.: US 7,028,689 B2**
(45) **Date of Patent: Apr. 18, 2006**

(54) **FILTERING FACE MASK THAT USES AN EXHALATION VALVE THAT HAS A MULTI-LAYERED FLEXIBLE FLAP**

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(73) Assignee: **3M Innovative Properties Company**, St. Paul, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 516 days.

(21) Appl. No.: **09/989,965**

(22) Filed: **Nov. 21, 2001**

(65) **Prior Publication Data**

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(51) **Int. Cl.**
A62B 9/02 (2006.01)
A62B 18/10 (2006.01)

(52) **U.S. Cl.** **128/205.24**; 128/207.12

(58) **Field of Classification Search** 128/203.11, 128/205.24, 206.15, 207.16; 137/855–858
See application file for complete search history.

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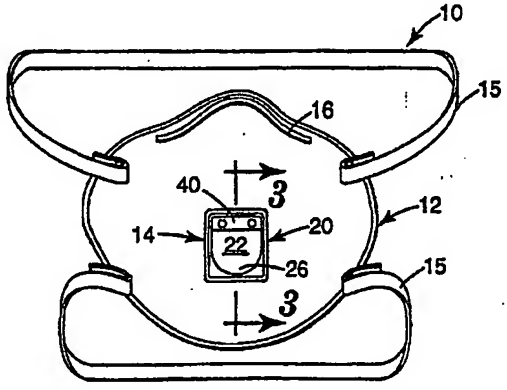
Primary Examiner—Henry Bennett
Assistant Examiner—Teena Mitchell
(74) *Attorney, Agent, or Firm*—Karl G. Hanson

(57) **ABSTRACT**

A filtering face mask that includes a mask body and an exhalation valve. The mask body is adapted to fit at least over the nose and mouth of a wearer to create an interior gas space when worn, and the exhalation valve is in fluid communication with the interior gas space. The exhalation valve comprises a valve seat that has a seal surface and an orifice through which an exhale flow stream may pass to leave the interior gas space. A flexible flap is mounted to the valve seat such that the flap makes contact with the seal surface when the valve is in its closed position and such that the flap can flex away from the seal surface during an exhalation to allow exhaled air to pass through the orifice to ultimately enter an exterior gas space. The flexible flap has at least first and second juxtaposed layers where at least one of the layers is stiffer or has a different elastic modulus than the other layer.

86 Claims, 3 Drawing Sheets



liner included to facilitate cutting. Upon separating the Finaprene™ 502 film from the release liner, the film thickness measured was 24 micrometers thick, very close to the thickness of the PET.

A cantilever bending test was used to indicate stiffness of thin strips of material by measuring the bending length of a specimen under its own mass. A test specimen was prepared by cutting the 0.794 cm wide strips of material to approximately 5 cm lengths. The specimen was slid, in a direction parallel to its long dimension, over the 90° edge of a horizontal surface. After 1.5 cm of material was extended past the edge, the overhang of the specimen was measured as the vertical distance from the end of the strip to the horizontal surface. The overhanging distance of the specimen divided by its extended length was reported as the cantilever bend ratio. A cantilever bend ratio approaching 1 would indicate a high level of flexibility where a material with a bend ratio approaching 0 would be stiff.

TABLE 4

Material	Film Thickness (micrometer)	Cantilever Bend Ratio
Layer 1	24	0.95
Layer 2	23	0.26

Layer 1 - Finaprene ™ 502 film, containing 1% Atmer 1759.
Layer 2 - PET film of the same composition as Example 1.

The data set forth in Table 4 shows that the second layer is very stiff, relative to the first layer even though it is slightly not as thick.

Comparative Example 1

A valve, with its outer protective cover removed, from a commercially available 8511™ N95 respirator available from 3M Company, St. Paul, Minn. was evaluated using the test procedures described above. The valve seat that was used was the same as the valve seat used in Example 1. The flexible flap had a monolithic construction, which was the same as the flaps used in the commercially available 8511 ™ 3M mask. The flap was composed of polyisoprene. The flexible flap had the same dimensions as the flap used in Example 1 and had a material density of 1.08 grams per cubic centimeter (g/cm^3).

Leak Rate Test and Pressure Drop Test evaluations were also conducted on the inventive valve and the comparative valve. The values for the Pressure Drop are shown in FIG. 9. The Flap Mass, Leak Rate, Valve Efficiency, and Integrated Flap Activation Power are given below in Table 5. The valves represent the average of three test specimens for both the Example and the Comparative Example.

TABLE 5

Valve	Flap Mass (g)	Leak Rate (cm^3/min)	Integrated Flap Actuation Power (mW)	Valve Efficiency (mW g · cm^3/min)
Multi-layered flap valve	0.053	5.0	30	8
Single layer flap valve	0.279	5.7	48	76

The data, set forth in Table 5 and depicted in FIG. 9, show that a valve or face mask that employs the inventive technology requires significantly less (37% less) power to actuate, when compared to a face mask that uses a valve that has a single layered construction, over a functional range of flow rates. For both the individual flow points and over the operational range of flow points, a reduction in valve actuation power is important in use because the wearer's breathing is what actuates the valve. The greater the actuation power, especially over the functional range of the valve, the more difficult it is for the wearer to breathe when the mask is worn. Over long wearing periods, where a user might take ten to twelve breaths per minute through the mask, the compounding of the power consumption to actuate the valve becomes an important physiological factor in terms of breathing comfort and worker satisfaction. A mask that is more easily vented, through a valve that requires less power to actuate, is more efficient in removing carbon dioxide and moisture, which further improves wearer comfort and makes it more likely that the wearer will keep the mask donned to their face when in a toxic environment.

The data set forth in Table 5 also demonstrate that the invention may afford a 850% Valve Efficiency improvement over a comparative valve when operating in the functional range typical for filtering face masks. Considering that the Valve Efficiency parameter accounts for the counter balancing effects of leakage, valve mass, and actuation power, this is a particularly significant result. A valve designed for use with a face mask that employs a single layer material construction may require, when considered on an equivalent design basis, a heavier flap to more tightly close the valve. A flap that has a tighter seal and greater mass requires more power to actuate. In terms of the Valve Efficiency parameter, the required increase in mass and actuation power, offsets any efficiency gains for reduced leak rate.

It is also evident that the gains in performance were made with minimal use of material, as depicted by the mass of the flaps, an indication of the economy achievable with valve flaps of the invention.

All of the patents, patent applications, and other documents cited above, including those in the Background section, are incorporated by reference into this document in total.

The present invention may be suitably practiced in the absence of any element not specifically described in this document.

What is claimed is:

1. A filtering face mask that comprises:

(a) a mask body that is adapted to fit at least over the nose and mouth of a wearer to create an interior gas space when worn; and

(b) an exhalation valve that is in fluid communication with the interior gas space, the exhalation valve comprising:

(i) a valve seat that comprises a seal surface and an orifice through which exhaled air may pass to leave the interior gas space; and

(ii) a flexible flap that is mounted to the valve seat such that the flap makes contact with the seal surface when the valve is in a closed position and such that the flap can flex away from the seal surface during an exhalation to allow exhaled air to pass through the orifice to ultimately enter an exterior gas space, the flexible flap comprising at least first and second juxtaposed layers, wherein at least one of the first and second layers is stiffer than the other layer.

2. The filtering face mask of claim 1, wherein the first and second layers comprise first and second materials, respectively, that each have a different modulus of elasticity.

3. The filtering face mask of claim 2, wherein the first layer is disposed closer to the seal surface than the second layer when the flap is positioned against the seal surface, and wherein the second layer has a greater modulus of elasticity than the first layer.

US007025058B2

(12) **United States Patent**
Armstrong et al.

(10) **Patent No.: US 7,025,058 B2**
(45) **Date of Patent: Apr. 11, 2006**

(54) **METERED DOSE DELIVERY DEVICE FOR LIQUID AND POWDER AGENTS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 478 days.

(21) Appl. No.: **10/134,041**

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(65) **Prior Publication Data**

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Related U.S. Application Data

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A61M 15/00 (2006.01)
A61M 16/00 (2006.01)
A61M 15/08 (2006.01)

(52) **U.S. Cl.** **128/203.21**; 128/203.13; 128/203.15

(58) **Field of Classification Search** 128/200.22, 128/203.12, 203.15, 203.21
See application file for complete search history.

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Primary Examiner—Glenn Dawson
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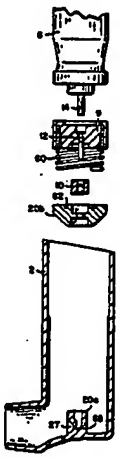
(57) **ABSTRACT**

A delivery device for the delivery of an agent to the mouth, nose or other bodily site of a user. The delivery device includes an aerosol canister that is actuated to expel propellant, which captures and disperses the agent. In a preferred embodiment, the propellant captures and disperses the agent into the mouth or nose of a user, and inhalation by the user directs the agent to the lungs of the user. The delivery device is particularly suitable for the treatment of bronchial asthma, respiratory conditions and for the delivery of systemically absorbed agents.

46 Claims, 18 Drawing Sheets



in the form of a soft, low velocity cloud that remains suspended and remains visible for greater than about 3 seconds post actuation.

Without being bound by theory, it is believed that the suspension of the mixture by the present device provides a higher respirable fraction of agent. With prior devices, for example, the propellant and agent mixture is expelled from the devices in a high velocity, liner stream. This high velocity, linear stream impinges on the back of the mouth and throat of the user. With the present device, on the other hand, the mixture is delivered to the mouth in a soft, low velocity, cloud-like formation that remains suspended as the user inhales and directs the mixture down the throat to the treatment area (e.g. lungs).

The foregoing description of the invention is merely illustrative thereof, and it is understood that variations and modifications can be effected without departing from the scope or spirit of the invention as set forth in the following claims.

What is claimed is:

1. A device for delivery of at least one dose of an agent comprising:

a body member having at a first end a canister housing a propellant and a second end adapted for insertion into the mouth or nose of a user;

a container within the body member, for holding the dose of agent, wherein the container is positioned between the canister and second end; and

a mechanism for exposing the dose of agent in the container to the propellant, the mechanism positioned between the canister and the container;

whereby as the canister is moved towards the container, (i) the mechanism passes through the container thereby carrying the dose of agent towards the second end, and (ii) the canister is actuated to expel the propellant and the dose of agent from the mechanism into the mouth or nose of the user.

2. A delivery device kit, comprising one or more of the delivery devices of claim 1 and one or more a containers each holding at least one dose of agent.

3. The device of claim 1, wherein the mechanism is sized to carry a precise dose of agent to the second end.

4. The device of claim 1, wherein the size of the mechanism controls the dose of agent delivered by the device.

5. The device of claim 1, wherein the mechanism is a piercing member.

6. The device of claim 5, whereby as the canister is moved towards the container, the piercing member passes through the container, thereby carrying the dose of agent towards the second end.

7. The device of claim 6, wherein at least the tip portion of the piercing member is hollow and the dose of agent is picked up within the hollow portion of the piercing member.

8. The device of claim 7, wherein the inner diameter of the piercing member is sized to pick up a precise dose of agent.

9. The device of claim 7, wherein the size of the inner diameter of the piercing member controls the dose of agent delivered by the device.

10. The device of claim 8, wherein the inner diameter of the piercing member ranges from about 0.005" to about 0.1".

11. The device of claim 8, wherein the inner diameter of the piercing member ranges from about 0.01" to about 0.08".

12. The device of claim 8, wherein the canister is connected to the piercing member such that the propellant is expelled from the canister through the hollow portion of the piercing member, thereby expelling the dose of agent from the piercing member.

13. The device of claim 5, wherein the piercing member is a needle.

14. The device of claim 5, wherein the piercing member is sharpened at the piercing end to about a 30° to 60° angle and the rim of the piercing member opposite the apex is blunted.

15. The device of claim 1, wherein the thickness of the container holding the agent controls the dose of agent delivered by the device.

16. The device of claim 5, wherein the container is partially filled with the dose of agent.

17. The device of claim 16, wherein the dose of agent is housed within at least one compartment within the container.

18. The device of claim 17, wherein the dose of agent is housed within a single center compartment within the container.

19. The device of claim 17 or 18, wherein the at least one compartment is cylindrically shaped.

20. The device of claim 17, wherein the at least one compartment has a cross section approximately the same as the cross section of the piercing member to minimize ahy residue of the dose of agent in the container.

21. The device of claim 18, wherein the height of the at least one compartment housing the dose of agent controls the dose of agent delivered by the device.

22. The device of claim 17, wherein a plurality of compartments each for housing a dose of agent are positioned in a circle within the container.

23. The device of claim 22, further comprising a rotating mechanism for rotating the container such that each of the plurality of compartments may be lined up with the piercing member.

24. The device of claim 23, further comprising a locking mechanism for locking the container into place during rotation, whereby the locking mechanism locks the container in place each time a compartment is lined up with the piercing member.

25. The device of claim 1, wherein a dose of agent ranges from about 5 μg to about 30 mg.

26. The device of claim 1, wherein a dose of agent ranges from about 10 μg to about 20 mg.

27. The device of claim 1, wherein the dose of agent comprises finely divided particles, the finely divided particles having diameters ranging from about 1 micron to about 50 microns.

28. The device of claim 1, wherein the dose of agent comprises finely divided particles, the finely divided particles having diameters ranging from about 3 microns to about 50 microns.

29. The device of claim 1, wherein the dose of agent is one or more medicinal agent.

30. The device of claim 1, wherein the close of agent is a liquid.

31. The device of claim 5, further comprising at least one bypass pathway extending from the canister, around the dose of agent in the container and towards to second end, whereby at least a portion of the propellant travels through the at least one bypass pathway and at least a portion of the propellant travels through the container and carries the dose of agent towards the second end.

32. The device of claim 31, wherein the portion of the propellant in the bypass pathway mixes with a portion of the propellant that travels through the container, and thereby assists in delivering the dose of agent to the mouth or nose of a user.

33. The device of claim 31 or 32, further comprising swirl chamber into which the dose of agent from the container and

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(12) **United States Patent**
Tinsley

(10) **Patent No.: US 7,020,918 B1**
(45) **Date of Patent: Apr. 4, 2006**

(54) **CUSHION SET FOR POSITIONING A HUMAN BODY**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **11/080,084**

(22) Filed: **Mar. 14, 2005**

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A47C 16/00 (2006.01)

(52) **U.S. Cl.** **5/632**; 5/630; 5/638; 5/725; 5/731; 5/652; 5/657

(58) **Field of Classification Search** 5/630, 5/632, 638, 620, 731, 733–735, 725, 652, 5/657, 900.5, 922
See application file for complete search history.

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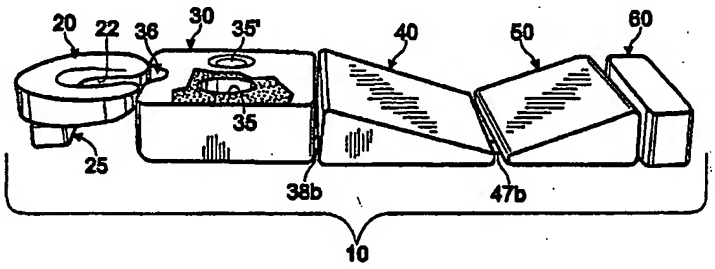
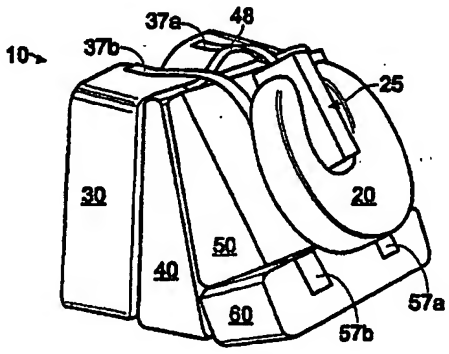
(57) **ABSTRACT**

A cushion set for positioning a human body, including a face support cushion, a spacer block cushion, an upper torso support cushion, a lower torso support cushion, a calf support cushion and a bolster. The face support cushion is generally in the shape of an inverted "U" having a generally inverted U-shaped opening passing therethrough. The upper torso support cushion is adapted to be releasably attached to the face support cushion, the lower torso support cushion is adapted to be releasably attached to the upper torso support cushion, the calf support cushion is adapted to be releasably attached to the lower torso support cushion, and the bolster is adapted to be releasably attached to the calf support cushion. The spacer block cushion is adapted to be releasably attached to the underside of the face support cushion.

7 Claims, 2 Drawing Sheets





thereof. The overall height of the upper end of lower torso support cushion **40** is substantially the same height as the overall height of the lower end of the upper torso support cushion **30**. The upper and lower foam sheet cushions **42** and **44** of lower torso support cushion **40** are covered with vinyl or a similar washable covering.

Calf support cushion **50** is comprised of upper and lower foam sheet cushions **52** and **54**, respectively. Upper foam sheet cushion **52** is triangular in cross-section along an imaginary plane passing perpendicularly through the upper and lower surfaces thereof between its upper and lower ends along the longitudinal axis thereof. The overall height of the lower end of calf support cushion **50** is substantially the same height as the overall height of the upper end of lower torso support cushion **40**. The upper and lower foam sheet cushions **52** and **54** of calf support cushion **50** are covered with vinyl or a similar washable covering.

Bolster support cushion **60** is substantially rectangular in cross-section along an imaginary plane passing perpendicularly through the upper and lower surfaces thereof between its upper and lower ends along the longitudinal axis thereof. The height of bolster support cushion **60** is substantially the same height as the overall height of the lower end of calf support cushion **50**. Bolster support cushion **60** is formed of a foam block covered with vinyl or a similar washable covering.

Support cushions **30, 40, 50** and **60** have substantially the same width and the right and left sides thereof are in substantial alignment during use. The overall height of upper torso support cushion **30** and bolster **60**, as well as the overall height of the upper end of lower torso support cushion **40** and the overall height of the lower end of calf support cushion **50**, are substantially identical.

The various support cushions **20, 25, 30, 40, 50** and **60** comprising cushion set **10** are removably connectable to each other, and the distance between them can be varied, by means of hook and loop fastener means, such as those sold under the trademark "VELCRO". Herein, one component of a hook and loop fastener means will be referred to as "hook or loop fastener component", while the adjacent mating component will be referred to as "loop or hook fastener component".

FIG. **3** is a bottom plan view of the various cushions disconnected from each other in order to better show the various hook and loop fasteners and their positions.

Face support cushion **20** has hook or loop fastener components **24***a* and **24***b* located on the right and left sides thereof, and hook or loop fastener component **24***c* located on the upper end thereof, all being located on the underside of face support cushion **20**.

Spacer block **25** has a loop or hook fastener component **26** located in a mid-portion of the underside thereof and adapted to releasably engage hook or loop fastener component **24***c* of face support cushion **20**.

Upper torso support cushion **30** has upper right and left loop or hook fastener straps **37***a* and **37***b* extending outwardly from the upper end thereof and adapted to releasably engage right and left hook or loop fastener components **24***a* and **24***b* of face support **20**, respectively. Upper torso support cushion **30** has lower right and left loop or hook fastener straps **38***a* and **38***b* whose inner ends are attached to the underside of the lower end of upper torso support cushion **30**.

Lower torso support cushion **40** has right and left hook or loop fastener components **46***a* and **46***b* attached to the underside of the upper end of lower torso support cushion **40**, and adapted to releasably engage right and left loop or hook fastener straps **47***a* and **47***b* of upper torso support cushion **30**, respectively. Lower torso support cushion **40** has right and left loop or hook fastener straps **47***a* and **47***b* whose inner ends are attached to the underside of the lower end of lower torso support cushion **40**.

Calf support cushion **50** has right and left hook or loop fastener components **56***a* and **56***b* attached to the underside of the upper end of calf support cushion **50**, and adapted to releasably engage right and left loop or hook fastener straps **47***a* and **47***b* of lower torso support cushion **40**. Calf support cushion **50** has right and left loop or hook fastener straps **57***a* and **57***b* whose inner ends are attached to the underside of the lower end of calf support cushion **50**.

Bolster support cushion **60** has right and left hook or loop fastener components **62***a* and **62***b* attached to the underside thereof, and adapted to releasably engage right and left loop or hook fastener straps **57***a* and **57***b*, respectively.

Right hook or loop fastener components **24***a*, **46***a*, **56***a*, and **62***a*, as well as right loop or hook fastener straps **37***a*, **38***a*, **47***a*, and **57***a* all substantially lie in a common plane, i.e., are substantially in alignment with each other. Similarly, left hook or loop fastener components **24***b*, **46***b*, **56***b*, and **62***b*, as well as left loop or hook fastener straps **37***b*, **38***b*, **47***b*, and **57***b* all substantially lie in a common lane, i.e., are substantially in alignment with each other.

In use, the various support components are placed upon a support surface **12** in the order described, and right and left hook or loop fastener components are releasably engaged with adjacent right and left loop or hook fastener straps. The distance between the various support cushions can be adjusted to accommodate the location of the head, upper and lower torso of a particular user. Being fastened together, the various support components cannot slip out of place during use.

The support surface **12** can be any support surface, such as a massage table, medical examination table, floor, lounge chair, etc.

Although the cushion set **10** has been described relative to its use with the user lying face down, it can be used where the user is lying on his or her back.

When not in use, cushion set **10** can be folded down into the compact and easily portable configuration shown in FIG. **4**. As can be seen, the various cushions are releasably attached to each other in a manner adapted to allow the cushions to be folded up into a compact package with the upper torso support cushion **30** being in juxtaposition with the lower torso support cushion **40**, the lower torso support cushion **40** being in juxtaposition with the calf support cushion **50** and the bolster support cushion **60**, with the face support cushion **20** resting against calf support cushion **50**. With cushion set **10** in its folded position, handle **48** is located at the top of upper torso support cushion **40** to allow the folded-up cushion set **10** to be easily carried.

It will be obvious to those having skill in the art that many changes may be made to the details of the above-described embodiments of this invention without departing from the underlying principles thereof. The scope of the present invention should, therefore, be determined only by the following claims.

The invention claimed is:

1. A cushion set for positioning a human body comprising:

a face support cushion;

an upper torso cushion adapted to be releasably attached to said face support cushion, said upper torso cushion having an upper end, a lower end, and right and left sides, said upper torso cushion having a longitudinal axis extending between said upper and lower ends in a

mid-portion thereof, said upper torso cushion being substantially rectangular in cross-section in a plane passing perpendicularly therethrough along said longitudinal axis;

a lower torso cushion adapted to be releasably attached to the lower end of said upper torso cushion, said lower torso cushion having an upper end, a lower end, and right and left sides, said upper torso cushion having a longitudinal axis extending between said upper and lower ends in a mid-portion thereof, said upper torso cushion being substantially triangular in cross-section in a plane passing perpendicularly therethrough along said longitudinal axis, the base of said triangle being the upper end of said lower torso support cushion;

a calf support cushion adapted to be releasably attached to the lower end of said lower torso cushion, said calf support cushion having an upper end, a lower end, and right and left sides, said calf support cushion having a longitudinal axis extending between said upper and lower ends in a mid-portion thereof, said calf cushion being substantially triangular in cross-section in a plane passing perpendicularly therethrough along said longitudinal axis, the base of said triangle being the lower end of said calf support cushion; and

a bolster support cushion adapted to be releasably attached to the lower end said calf support cushion.

2. The cushion set of claim 1 wherein said face support cushion has an outer periphery generally in the shape of an inverted "U", said face support cushion having a generally inverted U-shaped opening passing therethrough for accommodating a user's eyes, nose and mouth when the user is lying face down on said cushion set.

3. The cushion set of claim 1 including a spacer block cushion adapted to be releasably attached to the underside of said face support cushion.

4. The cushion set of claim 1 wherein said upper torso cushion is releasably attached to said face support cushion, said lower torso cushion is releasably attached to said upper torso cushion, said calf support cushion is releasably attached to said lower torso cushion, and said bolster support cushion releasably attached to said calf support cushion all in a manner adapted to allow the space between said cushions to be adjusted.

5. The cushion set of claim 4 wherein said cushions are releasably attached to each other by hook and loop fastener means.

6. The cushion set of claim 1 wherein said cushions are releasably attached to each other in a manner adapted to allow said cushions to be folded-up into a compact package with said upper torso support cushion being in juxtaposition with said lower torso support cushion, said lower torso support cushion and said bolster support cushions being in juxtaposition with said calf support cushion, and said face support cushion resting against said calf support cushion.

7. The cushion set of claim 6 including a handle strap attached to said lower torso support cushion at a location adapted to allow the folded-up cushion set to be carried.

* * * * *

US006959710B2

(12) **United States Patent**
Barnett et al.

(10) **Patent No.: US 6,959,710 B2**
(45) **Date of Patent: Nov. 1, 2005**

(54) **NASAL MASK AND SYSTEM USING SAME**

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(73) Assignee: **Respironics, Inc.**, Murrysville, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(22) Filed: **Nov. 12, 2003**

(65) **Prior Publication Data**

US 2004/0094158 A1 May 20, 2004

Related U.S. Application Data

(63) Continuation of application No. 09/865,327, filed on May 25, 2001, now Pat. No. 6,651,663, which is a continuation-in-part of application No. 09/310,548, filed on May 12, 1999, now Pat. No. 6,412,488.

(51) **Int. Cl.**[7] **A62B 18/02**

(52) **U.S. Cl.** **128/207.13**; 128/205.25; 128/206.21

(58) **Field of Search** 128/205.25, 206.12, 128/206.18, 206.21, 206.27, 206.28, 207.12, 128/207.13

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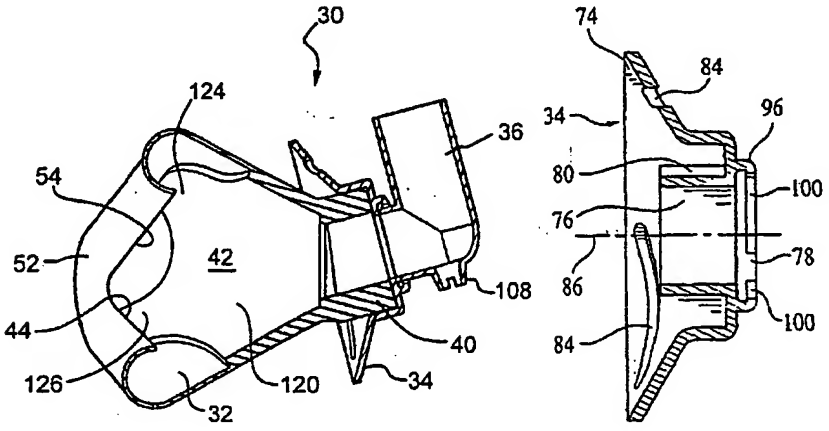
(74) *Attorney, Agent, or Firm*—Michael W. Haas

(57) **ABSTRACT**

The present invention discloses a nasal mask assembly that includes a seal member defined from a unitary piece of elastomeric material. The seal member defines a nose receiving cavity and has a first end portion and a second end portion generally opposite the first end portion. A first opening in the first end portion allows at least a portion of a nose to enter the nose receiving cavity such that the nares of the patient communicate with the nose receiving cavity. The seal member includes a neck portion defined in the second end portion and a second opening defined in the neck portion in communication with the nose receiving cavity. A reinforcement area is provided on the side walls of the seal member. The reinforcement area comprises a saddle shaped contoured area on each side of the seal member. Each saddle shaped area has an upper and a lower protrusion portion for providing supporting contact with the face.

8 Claims, 10 Drawing Sheets



In a preferred embodiment, exhaust port **108** is located relatively close to the nose receiving cavity in the seal member to minimize dead space. It is to be understood, however, that the present invention contemplates providing the exhaust port at other locations, including providing more than one exhaust port in the conduit coupling member. Furthermore, while exhaust port **108** is shown protruding from conduit coupling member **36**, it is to be understood that other configurations for the exhaust port are possible. For example, the exhaust port can be flush with the walls of the conduit coupling member, so that the exhaust port is merely a hole defined in the wall of the conduit coupling member. It is to be further understood that the exhaust port can have other configurations, including any that of any conventional port.

Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims.

What is claimed is:

1. A patient interface device comprising:

(a) a collar defined from a relatively rigid material, the collar having an aperture defined in a central portion thereof, and a plurality of headgear attachment points disposed at a perimeter of the collar, wherein the aperture is defined in a first plane, and wherein at least one of the plurality of headgear attachment points is defined in a second plane that is disposed at a non-zero angle with respect to the first plane;

(b) an elbow coupling rotatably attached to the collar such that the elbow coupling rotates relative to the collar; and

(c) a cushion defined from a pliable material, having a generally triangular shape, and operatively attached to the collar such that the elbow coupling and the cushion are disposed on opposite sides of the collar, wherein a nose receiving cavity is defined in the cushion, and wherein the cushion comprises:

(1) a proximal portion operatively coupled to the collar and having a first opening defined therein, wherein the first opening and the aperture provide a path for communicating the nose receiving cavity with an interior of the elbow coupling, and

(2) a side wall extending from the proximal portion and terminating generally at a distal portion that is adapted to contact a patient responsive to the patient interface device being donned by a patient, wherein the distal portion includes a second opening defined therein that is sized and configured to receive at least a portion of a nose of such a patient so that nares of such a patient communicate with the nose receiving cavity, and wherein the distal portion of the side wall provides a rounded patient portion.

2. The patient interface device according to claim **1**, wherein the elbow coupling includes an exhaust port defined therein.

3. The patient interface device according to claim **1**, wherein the distal portion of the cushion includes an inturned lip having an edge that is generally turned toward the nose receiving cavity.

4. The patient interface device according to claim **1**, wherein the collar is arranged and configured such that the plurality of headgear attachment points are maintained in a spaced apart relation from the cushion to minimize contact between headgear straps that are attachable to the collar at the plurality of headgear attachment points and the cushion responsive to the patient interface device, including such headgear straps, being donned by a patient.

5. The patient interface device according to claim **1**, wherein the distal portion is contoured to correspond to a facial structure of a human.

6. The patient interface device according to claim **1**, wherein the elbow coupling includes a substantially ninety degree bend and an exhaust port defined therein.

7. The patient interface device according to claim **1**, wherein the cushion is sized such that an uppermost portion of the distal portion overlies a nose of a patient, and a lowermost portion of the distal portion overlies area of such a patient above an upper lip and below such a patient's nares, responsive to the patient interface device being donned by such a patient.

8. The patient interface device according to claim **1**, wherein the side wall includes a reinforcement area of increased thickness, wherein the reinforcement area is integrally formed on the side walls and extends around a perimeter of the cushion, and wherein the reinforcement area includes a first saddle shaped portion disposed on a first side of the cushion generally proximate to the distal portion and a second saddle shaped portion disposed on a second side of the cushion also generally proximate to the distal portion, wherein each of the first and the second saddle shaped portions includes a plurality of protrusions extending from the second end portion with a notch therebetween, and wherein a distal edge of the reinforcement area is continuous and spans a circumference of the cushion.

* * * * *

EXHIBIT B

Excerpt from Merriam-Webster's

Collegiate Dictionary (Tenth Edition)

Merriam-Webster's Collegiate® Dictionary

TENTH EDITION

Merriam-Webster, Incorporated
Springfield, Massachusetts, U.S.A.

mi·cro·pro·ces·sor \ˌmī-krō-ˈprä-ˌse-sər, -ˈprō-\ *n* (1970) : a computer processor contained on an integrated-circuit chip; *also* : such a processor with memory and associated circuits

mi·cro·pro·gram \-ˈprō-ˌgram, -grəm\ *n* (1953) : a routine composed of microinstructions used in microprogramming

mi·cro·pro·gram·ming \-ˌgra-miŋ\ *n* (1953) : the use of routines stored in memory rather than specialized circuits to control a device (as a computer)

mi·cro·pro·jec·tor \-prə-ˈjek-tər\ *n* (1927) : a projector utilizing a compound microscope for projecting on a screen a greatly enlarged image of a microscopic object — **mi·cro·pro·jec·tion** \-ˈjek-shən\ *n*

mi·cro·pub·lish·ing \-ˈpə-bli-shiŋ\ *n* (1966) : publishing in microform — **mi·cro·pub·lish·er** \-bli-shər\ *n*

mi·cro·pul·sa·tion \-ˌpəl-ˈsā-shən\ *n* (1949) : a pulsation having a short period ⟨a ~ of the earth's magnetic field with a period in the range from a fraction of a second to several hundred seconds⟩

mi·cro·punc·ture \-ˈpəŋ(k)-chər\ *n* (1948) : an extremely small puncture (as of a nephron); *also* : an act of making a micropuncture

mi·cro·pyle \ˈmī-krə-ˌpīl\ *n* [F, fr. *micr-* + Gk *pylē* gate] (1821) 1 : a minute opening in the integument of an ovule of a seed plant 2 : a differentiated area of surface in an egg through which a sperm enters

mi·cro·py·lar \ˌmī-krə-ˈpī-lər\ *adj*

mi·cro·quake \ˈmī-krō-ˌkwāk\ *n* (1967) : MICROEARTHQUAKE

mi·cro·ra·di·o·gra·phy \ˌmī-krō-ˌrā-dē-ˈä-grə-fē\ *n* (1913) : radiography in which an X-ray photograph is prepared showing minute internal structure — **mi·cro·ra·dio·graph** \-ˈrā-dē-ə-ˌgraf\ *n* — **mi·cro·ra·dio·graph·ic** \-ˌrā-dē-ə-ˈgra-fik\ *adj*

mi·cro·read·er \ˈmī-krō-ˌrē-dər\ *n* (1949) : an apparatus that gives an enlarged image of a microphotograph esp. for reading

mi·cro·re·pro·duc·tion \ˌmī-krō-ˌrē-prə-ˈdək-shən\ *n* (1938) : the reproduction of written or printed matter in microform; *also* : an item so reproduced

mi·cro·scale \ˈmī-krō-ˌskāl\ *n* (1931) : a very small scale

mi·cro·scope \ˈmī-krə-ˌskōp\ *n* [NL *microscopium*, fr. *micr-* + *-scopium* -scope] (1654) 1 : an optical instrument consisting of a lens or combination of lenses for making enlarged images of minute objects; *esp* : COMPOUND MICROSCOPE 2 : an instrument using radiations other than light or using vibrations for making enlarged images of minute objects ⟨acoustic ~⟩

mi·cro·scop·ic \ˌmī-krə-ˈskä-pik\ *or* **mi·cro·scop·i·cal** \-pi-kəl\ *adj* (1732) 1 : resembling a microscope esp. in perception 2 a : invisible or indistinguishable without the use of a microscope b : very small or fine or precise 3 : of, relating to, or conducted with the microscope or microscopy — **mi·cro·scop·i·cal·ly** \-pi-k(ə-)lē\ *adv*

mi·cros·co·py \mī-ˈkräs-kə-pē\ *n* (ca. 1665) : the use of or investigation with the microscope — **mi·cros·co·pist** \-pist\ *n*

mi·cro·sec·ond \ˈmī-krō-ˌse-kənd, -ˌkänt\ *n* [ISV] (1906) : one millionth of a second

mi·cro·seism \ˈmī-krə-ˌsī-zəm\ *n* [ISV *micr-* + Gk *seismos* earthquake — more at SEISMIC] (1887) : a feeble rhythmically and persistently recurring earth tremor — **mi·cro·seis·mic** \ˌmī-krə-ˈsīz-mik, -ˈsīs-\ *adj* — **mi·cro·seis·mic·i·ty** \-sīz-ˈmi-sə-tē, -sīs-\ *n*

mi·cro·some \ˈmī-krə-ˌsōm\ *n* [G *Mikrosom*, fr. *mikr-* micr- + *-som* -some] (1885) 1 : any of various minute cellular structures (as a ribosome) 2 : a particle in a particulate fraction that is obtained by heavy centrifugation of broken cells and consists of various amounts of ribosomes, fragmented endoplasmic reticulum, and mitochondrial cristae — **mi·cro·som·al** \ˌmī-krə-ˈsō-məl\ *adj*

mi·cro·spec·tro·pho·tom·e·ter \ˌmī-krə-ˌspek-trō-fō-ˈtä-mə-tər\ *n* (1949) : a spectrophotometer adapted to the examination of light transmitted by a very small specimen (as a single organic cell) — **mi·cro·spec·tro·pho·to·met·ric** \-ˌfō-tə-ˈme-trik\ *adj* — **mi·cro·spec·tro·pho·tom·e·try** \-fō-ˈtä-mə-trē\ *n*

mi·cro·sphere \ˈmī-krə-ˌsfir\ *n* (1894) : a minute sphere — **mi·cro·spher·i·cal** \ˌmī-krə-ˈsfir-i-kəl, -ˈsfer-\ *adj*

mi·cro·spo·ran·gi·um \ˌmī-krō-spə-ˈran-jē-əm\ *n* [NL] (1881) : a sporangium that develops only microspores — **mi·cro·spo·ran·gi·ate** \-jē-ət\ *adj*

mi·cro·spore \ˈmī-krə-ˌspōr, -ˌspȯr\ *n* [ISV] (1858) : any of the spores in heterosporous plants that give rise to male gametophytes and are generally smaller than the megaspore — **mi·cro·spo·rous** \ˌmī-krə-ˈspōr-əs, -ˈspȯr-; mī-ˈkräs-pə-rəs\ *adj*

mi·cro·spo·ro·cyte \-ˈspōr-ə-ˌsīt, -ˈspȯr-\ *n* (1940) : a microspore mother cell

mi·cro·spo·ro·gen·e·sis \ˌmī-krə-ˌspōr-ə-ˈje-nə-səs, -ˌspȯr-\ *n* [NL] (1921) : the formation and maturation of microspores

mi·cro·spo·ro·phyll \-ˌfil\ *n* (ca. 1890) : a sporophyll that develops only microsporangia

mi·cro·state \ˈmī-krō-ˌstāt\ *n* (1962) : a nation that is extremely small in area and population

mi·cro·struc·ture \ˈmī-krō-ˌstrək-chər\ *n* [ISV] (1885) : the microscopic structure of a material (as a mineral or a biological cell) — **mi·cro·struc·tur·al** \ˌmī-krō-ˈstrək-chə-rəl, -ˈstrək-shrəl\ *adj*

mi·cro·sur·gery \ˌmī-krō-ˈsərj-rē, -ˈsər-jə-\ *n* (1926) : minute dissection or manipulation (as by a micromanipulator or laser beam) of living structures or tissue — **mi·cro·sur·gi·cal** \-ˈsər-ji-kəl\ *adj*

mi·cro·switch \-ˌswich\ *n* (1940) : a very small switch that is sensitive to minute motions and is used esp. in automatic devices

mi·cro·tech·nique \ˌmī-krō-tek-ˈnēk\ *also* **mi·cro·tech·nic** \-ˈtek-nik, -tek-ˈnēk\ *n* [ISV] (1892) : any of various methods of handling and preparing material for microscopic observation and study

mi·cro·tome \ˈmī-krə-ˌtōm\ *n* [ISV] (1856) : an instrument for cutting sections (as of organic tissues) for microscopic examination

mi·cro·tone \ˈmī-krə-ˌtōn\ *n* (1920) : a musical interval smaller than a halftone — **mi·cro·to·nal** \ˌmī-krə-ˈtō-nᵊl\ *adj* — **mi·cro·to·nal·i·ty** \-tō-ˈna-lə-tē\ *n* — **mi·cro·to·nal·ly** \-ˈtō-nᵊl-ē\ *adv*

mi·cro·tu·bule \ˌmī-krō-ˈtü-(ˌ)byül\ *n* (1961) : any of the minute tubules in eukaryotic cytoplasm that are composed of the protein tubulin and form an important component of the cytoskeleton, mitotic spindle, cilia, and flagella — **mi·cro·tu·bu·lar** \-ˈbyə-lər\ *adj*

mi·cro·vas·cu·lar \-ˈvas-kyə-lər\ *adj* (1959) : of, relating to, or constituting the part of the circulatory system made up of minute vessels (as venules or capillaries) that average less than 0.3 millimeters in diameter — **mi·cro·vas·cu·la·ture** \-lə-ˌchür, -ˌtyür, -ˌtür\ *n*

mi·cro·vil·lus \-ˈvi-ləs\ *n* [NL] (1953) : a microscopic projection of tissue, cell, or cell organelle; *esp* : any of the fingerlike outward projections of some cell surfaces — **mi·cro·vil·lar** \-ˈvi-lər\ *adj* — **mi·cro·vil·lous** \-ˈvi-ləs\ *adj*

mi·cro·volt \ˈmī-krə-ˌvōlt\ *n* (1868) : one millionth of a volt

mi·cro·watt \-ˌwät\ *n* (ca. 1909) : one millionth of a watt

¹mi·cro·wave \-ˌwāv\ *n, often attrib* (1931) 1 : a comparatively short electromagnetic wave; *esp* : one between about 1 millimeter and 1 meter in wavelength 2 : MICROWAVE OVEN

²microwave *vt* (1973) : to cook or heat in a microwave oven — **mi·cro·wav·able** *or* **mi·cro·wave·able** \ˌmī-krə-ˈwā-və-bəl\ *adj*

microwave oven *n* (1963) : an oven in which food is cooked by the heat produced by the absorption of microwave energy by water molecules in the food

mi·cro·world \-ˌwərld\ *n* (1955) : a small universe; *specif* : the natural universe observed at the microscopic or submicroscopic level

mic·tu·rate \ˈmik-chə-ˌrāt, ˈmik-tə-\ *vi* **-rat·ed; -rat·ing** [L *micturire*, fr. *meīere* to urinate; akin to OE *mīgan* to urinate, Gk *omeichein*] (1842) : URINATE — **mic·tu·ri·tion** \ˌmik-chə-ˈri-shən, ˌmik-tə-\ *n*

¹mid \ˈmid\ *adj* [ME, fr. OE *midde*; akin to OHG *mitti* middle, L *medius*, Gk *mesos*] (bef. 12c) 1 : being the part in the middle or midst ⟨in ~ ocean⟩ — often used in combination ⟨*mid*-August⟩ 2 : occupying a middle position ⟨the ~ finger⟩ 3 *of a vowel* : articulated with the arch of the tongue midway between its highest and its lowest elevation — **mid** *adv*

²mid *prep* (1808) : AMID

mid-air \ˈmid-ˈar, -ˈer\ *n* (1667) : a point or region in the air not immediately adjacent to the ground ⟨planes collided in ~⟩

Mi·das \ˈmī-dəs\ *n* [L, fr. Gk] : a legendary Phrygian king who is given the power of turning everything he touches to gold

Midas touch *n* (1883) : an uncanny ability for making money in every venture

mid·brain \ˈmid-ˌbrān\ *n* (1875) : the middle of the three primary divisions of the developing vertebrate brain or the corresponding part of the adult brain — called also *mesencephalon*; see BRAIN illustration

mid-course \-ˈkōrs, -ˈkȯrs\ *adj* (ca. 1956) : being or occurring in the middle part of a course (as of a spacecraft) ⟨a ~ correction⟩

mid-day \ˈmid-ˌdā, -ˈdā\ *n, often attrib* (bef. 12c) : the middle of the day

mid·den \ˈmi-dᵊn\ *n* [ME *midding*, of Scand origin; akin to ON *myki* dung & ON *dyngja* manure pile — more at DUNG] (14c) 1 : DUNGHILL 2 a : a refuse heap; *esp* : KITCHEN MIDDEN b : a small pile (as of seeds, bones, or leaves) gathered by a rodent (as a pack rat)

¹mid-dle \ˈmi-dᵊl\ *adj* [ME *middel*, fr. OE; akin to OE *midde*] (bef. 12c) 1 : equally distant from the extremes : MEDIAL, CENTRAL ⟨the ~ house in the row⟩ 2 : being at neither extreme : INTERMEDIATE 3 *cap* a : constituting a division intermediate between those prior and later or upper and lower ⟨*Middle* Paleozoic⟩ b : constituting a period of a language or literature intermediate between one called *Old* and one called *New* or *Modern* ⟨*Middle* Dutch⟩ 4 *of a verb form or voice* : typically asserting that a person or thing both performs and is affected by the action represented

²middle *n* (bef. 12c) 1 : a middle part, point, or position 2 : the central portion of the human body : WAIST 3 : the position of being among or in the midst of something 4 : something intermediate between extremes : MEAN 5 : the center of an offensive or defensive formation; *esp* : the area between the second baseman and the shortstop

middle age *n* (14c) : the period of life from about 40 to about 60 — **mid·dle-aged** \ˌmi-dᵊl-ˈājd\ *adj* — **mid·dle-ag·er** \-ˈā-jər\ *n*

Middle Ages *n pl* (1616) : the period of European history from about A.D. 500 to about 1500

Middle America *n* (1898) 1 : the region of the western hemisphere including Mexico, Central America, often the West Indies, and sometimes Colombia and Venezuela 2 : the midwestern section of the U.S. 3 : the middle-class segment of the U.S. population; *esp* : the traditional or conservative element of the middle class — **Middle American** *adj* — **Middle American** *n*

mid·dle·brow \ˈmi-dᵊl-ˌbrau\ *n* (1925) : a person who is moderately but not highly cultivated — **middlebrow** *adj*

middle C *n* (1840) : the note designated by the first ledger line below the treble staff and the first above the bass staff

mid·dle-class \ˌmi-dᵊl-ˈklas\ *adj* (1836) : of or relating to the middle class; *esp* : characterized by a high material standard of living, sexual morality, and respect for property — **mid·dle-class·ness** \-nəs\ *n*

middle class *n* (1766) : a class occupying a position between the upper class and the lower class; *esp* : a fluid heterogeneous socioeconomic grouping composed principally of business and professional people, bureaucrats, and some farmers and skilled workers sharing common social characteristics and values

middle distance *n* (1813) 1 : a part of a pictorial representation or scene between the foreground and the background 2 : any footrace distance usu. from 800 to 1500 meters or from 880 yards to one mile

Middle Dutch *n* (ca. 1959) : the Dutch language in use from about 1100 to about 1500 — see INDO-EUROPEAN LANGUAGES table

middle ear *n* (1852) : a small membrane-lined cavity that is separated from the outer ear by the eardrum and that transmits sound waves from the eardrum to the partition between the middle and inner ears through a chain of tiny bones

Middle English *n* (1830) : the English in use from the 12th to 15th centuries — see INDO-EUROPEAN LANGUAGES table

middle finger *n* (bef. 12c) : the midmost of the five digits of the hand

Middle French *n* (1889) : the French in use from the 14th to 16th centuries — see INDO-EUROPEAN LANGUAGES table

middle game *n* (1894) : the middle phase of a board game; *specif* : the part of a chess game after the pieces have been developed when players attempt to gain and exploit positional and material superiority — compare ENDGAME, OPENING

Middle Greek *n* (1889) : the Greek language used in the 7th to 15th centuries

middle ground *n* (1801) 1 : a standpoint midway between extremes 2 : MIDDLE DISTANCE 1

Middle High German *n* (1889) : the High German in use from about 1100 to 1500 — see INDO-EUROPEAN LANGUAGES table

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